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Chapter 1 Introduction

During our Medical Electronics degree we came across a wide range of diagnostic and therapeutic devices dealing with all aspects of human malfunction. From all those devices and processes, none is more exciting than the implantable devices, especially those dealing with our heart, the organ that never rests. Immersed into the body a pacemaker embodies the relationship of trust that has flourished between man and machine in the 20th century. Of all the human-machine relationships, it is one out of few that humans are totally dependent upon.

The commercial aspects of that relationship are not new and have been cleverly exploited. However, there is more to come with the privatisation of the healthcare services across Europe and the abolition of disturbing price caps and restrictions from national governments It is believed that customers will start paying more money than they do now for extending their lifetime.

Based upon this and the fact that heart related deaths are only second to strokes, it was decided to gain a deeper understanding of the aspects behind implantable devices. A pacemaker is the ideal starting point, as it has been established for 30 years with easy to grasp principles and objectives. The most feasible aspect for implementation within the time limits and resources of an MSc project was to get involved with the software behind pacing.

1.1 Aims and objectives

The aim of the project is to design and built a software and hardware model of a programmable VVI pacemaker. The overall objective to be achieved was to make the system fire a pulse whenever there is no QRS or when it occurs at very long intervals.
This has been done in practice for the last thirty years. The new thing here, is that it is implemented on a Digital Signal Processor (DSP), giving the advantage of even more processing power at higher speeds if needed, an advantage that was not fully utilised by this work mostly due to time constraints and inexperience. However, established ideas were implemented in a new and fast machine like the Texas Instruments ‘C6211 DSP setting a useful basis for further work to be done by another student.

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1.2 Overview of the project

The signal that is supposed to be the heart signal, was taken from a heart simulator (Laerdal, Heartsim2000). This has an extensive electrocardiogram (ECG) library with very accurate representations of seven QRS types, thirteen basic rhythms and five ventricular premature complexes.

The signal being a realistic ECG output was of very small amplitude of around 2 mV pk-pk and needed amplification. An amplifier was therefore build for three purposes, as an anti-alias measure for the interface with the analog-to-digital converter (ADC), an amplifier and filter for the ECG signal, and also to couple with the very high impedance of the input signal. The amplifier consisted of two op-amps acting as pre-amplifiers, an instrumentation amplifier and a Bessel 2nd order bandpass filter (9-40 Hz).

The amplifier output was connected to the DSP via an ADC and serial port. At the processing stage, the ECG signal was stripped out apart from its QRS complex, as only the ventricular activity is sensed by a VVI pacemaker. According to the decision rules applied a pacing pulse fires or not. The rule of thumb used was that the pacemaker should become active whenever the interval between QRS complexes becomes larger than 1 sec (less than 60 bpm). Some tolerance was added, to accommodate for normal heart variability. The resulting pacing pulses were diplayed in the same chart with the QRS complexes. The display consisted of a data acquisition card hosted in a Pentium PC, and running on an in-house made program called TCSCOPE.

As the project tries to emulate a VVI pacemaker only signals sensed from the ventricles are of interest. An intracardiac electrogram interpretation depends on the catheter location. A catheter placed on the right ventricle show a V wave. That corresponds to the QRS wave on the surface ECG. By stripping out the ECG signal apart from its QRS complex an accurate representation of intracardiac ventricle signal is achieved. Extraction of the QRS complex from the ECG signal was achieved with a high degree of consistency.

A general block diagram is shown to help you visualise the process (Figure 1.1).

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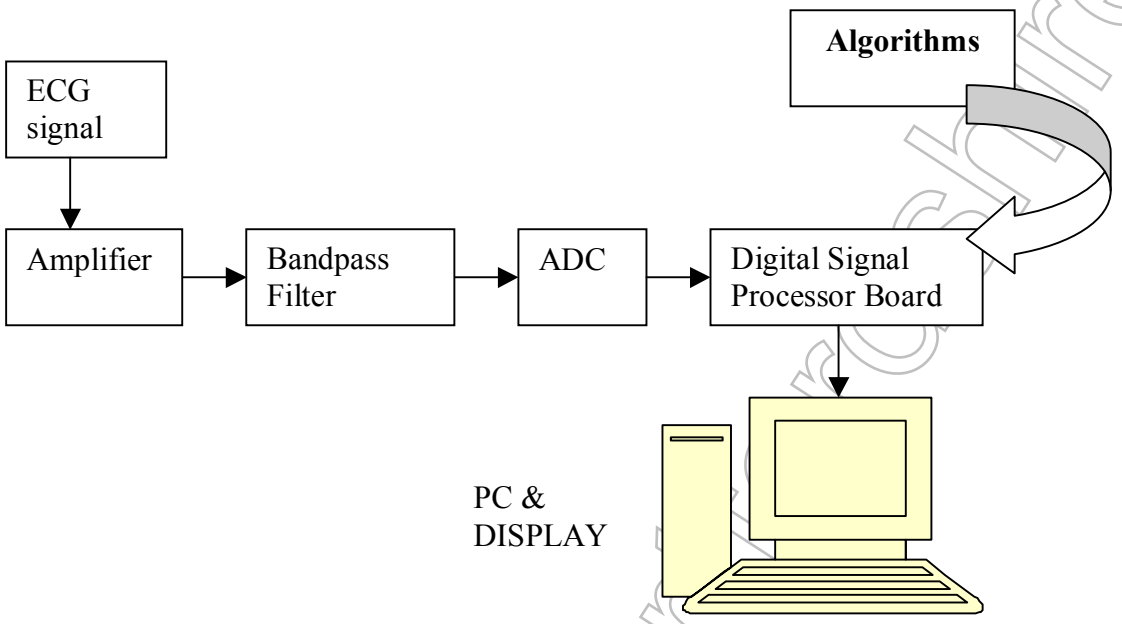

Figure 1.1 General Block Diagram

1.3 Guide to the Report.

Chapter 2 is a brief introduction to **electrocardiography** and the importance of the ECG signal in diagnosis. It covers a brief description of heart anatomy and function and then proceeds to define the five waves (P,Q,R,S and T) that constitute the ECG signal and their correlation to heart activity. A definition of what constitutes a healthy heart rate and its correlation to the cardiac output finishes the chapter.

Chapter 3 introduces the concepts behind **pacemakers** and their functions. It starts with the indications of abnormalities of heart activity that lead to the prescription of pacemakers. Atrio-Ventricular blocks are explained in some detail among other indications and their ECG characteristics are highlighted. The VVI pacemaker is defined and its principles of operation are explained in detail. The chapter finishes with the description of the different modalities of pacemakers as formulated by North American Society of Pacing and Electrophysiology (NASPE) association.

Chapter 4 is a small section introducing the Laerdal Heartsim 2000, the **heart simulator**. The variety of different ECG waveforms are mentioned. A more detailed definition of the basic rhythms and premature complexes can be found in Appendix 1.

Chapter five finishes the section of background material by introducing the **DSP** board (‘C6211) and development tools that come with it. It is a 150 MHz DSP from Texas Instruments. A few things about its internal architecture are presented with bias towards its

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memory organisation. The contents of the starter kit used follow next and presentation proceeds by illustrating the tools available for debugging the software. The chapter closes with a critical evaluation of the usefulness of the 'C6211 in relation with the requirements of the project. In appendix 2 there is a very useful list for fellow students detailing all the problems encountered during the project concerning the DSP as well as some ways to overcome them are also included.

In chapter 6 the biopotential **amplifier** is presented. Its general specifications and basic requirements are deployed in order to create the framework upon which the design choices were made. The ECG signal characteristics are revisited. A differential amplifier and a band-pass filter together with some extra gain make up the design. A detailed schematic diagram is explained. Results before and after amplification are shown.

Chapter 7 outlines the development of **software** employed and written to perform the signal processing. After a brief on the requirements of such a real-time task, the "audio" example utilised by the project is explained in detail. A reference to the "pipes" used to transfer data, and a comprehensive data path flow are presented. The sampling rate question is discussed.

Presentation of the algorithm developed and "embedded" into the audio example follows. The threshold detection part of the algorithm and why under laboratory conditions it proved so reliable is discussed. The critical part of the pacemaker timing cycles is discussed in full detail. When to start and stop pacing together with updating intervals of pulses and calculating their average interval are matters on which the discussion develops. A flowchart accompanies the discussion.

In Chapter 7 presentation of the work done during the project ends. Chapter 8 presents the **results** obtained from the system. QRS types on their default rhythms are tested first and there is evidence that the system does not recognise bundle branch blocks. All other types are recognised successfully. Then for each QRS type successfully recognised all the basic rhythms available are presented as inputs to the system. The system is found to respond in line with the expectations in all cases. When pacing is needed it is activated and inhibited when it is not. Emphasis is given on AV blocks. Their conduction ratios and the responses of the pacemaker are explained in detail. Graphs are included when necessary to help the reader visualise the processes and timings involved. Premature beats are then tested as inputs and they illicit a single pacing pulse. Their physiologic origin is briefly explained. And finally waveforms with noise are presented and the system output is found undistorted and satisfactory.

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Chapter 2 Electrocardiography

The purpose of this chapter is to provide a basic discussion of the physiological aspects behind pacing. Most of the material presented here, can be found in Aston[1]. For further information refer there or any other physiologic and/or biomedical instrumentation textbook.

2.1 Cardiac Anatomy and Function

The function of the heart is that of a double pump, working in unison. The right heart receives unoxygenated blood from venous system and sends unoxygenated blood to lungs. The left heart receives oxygenated blood from lungs and sends oxygenated blood to systemic circulation.

The heart is located between the lungs. Its base consists of two atria and its apex consists of two ventricles (see Figure 2.1). The ventricles are the "pumping" chambers.

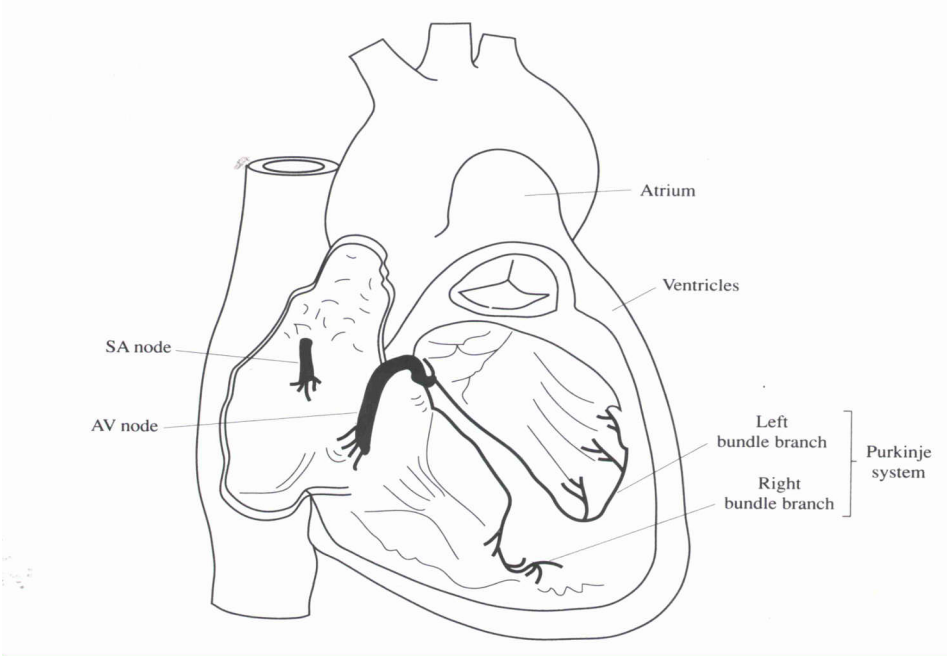

Figure 2.1: The depolarisation path through heart. Source Aston[1].

2.2 Biopotentials in the Heart

The **sinoatrial (SA) node** beats at a rate of from 70 to 80 beats per minute (bpm) at rest; the atrioventricular (AV) node and the bundle branch beat at lower rhythms. The SA node normally determines the heart rate and causes stimulation of the other tissue before it reaches its self-pacing threshold. The ability of the SA node to initiate an action potential without external stimulation is called automaticity.

The depolarisation of the SA node spreads through the atrium and reaches the AV node in about 40 msec. Because of the low conduction velocity of the AV node tissue, it requires about 110 msec for the depolarisation to reach the bundle branches. The ventricles then contract, the right ventricle forcing blood into the lungs, the left ventricle pushing blood through the circulation system. The contraction period of the heart is called **systole**.

The action potentials in the ventricle hold for 200 to 250 msec. This relatively long time allows the ventricular contraction to force blood into the arteries. The heart then depolarises during a rest period, called **diastole**. Then the cycle repeats.

The heart pumps around 4-8 litres/minute.

2.3 The Electrocardiogram

During diastole, while the heart is at rest, all of the cells are polarised so that the potential inside each cell is negative with respect to the tissue not yet polarised. Depolarisation occurs first at the SA node, making the outside of the tissue negative with respect to the tissue not yet depolarised.

This imbalance results in an ionic current, I, causing the left arm (LA) to measure positive with respect to the right arm (RA). the resulting voltage is called the **P-wave**.

After about 90 msec, the atrium is completely depolarised, and the ionic current measured by lead I reduces to zero. The depolarisation then passes into the right ventricular muscle, depolarising it and making it negative relative to the still polarized left ventricular muscle. Again, the direction of current causes a positive voltage called the **R-wave**.

The complete waveform is called an **electrocardiogram** (ECG) with labels P,Q,R,S, and T. The P-wave arises from depolarisation of the atrium. The QRS complex arises from depolarisation of the ventricles. The magnitude of the R-wave within this complex is approximately 1 mV. The **T-wave** arises from repolarisation of the ventricle muscle.

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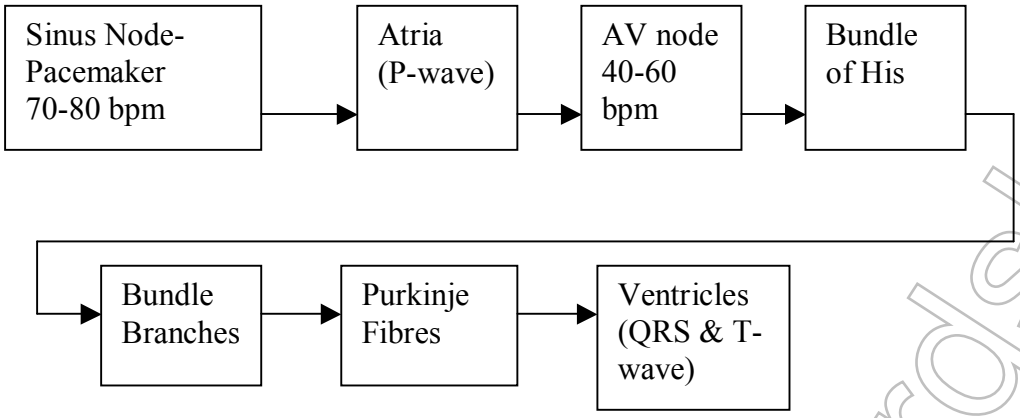

Figure 2.2: Normal Path of Impulse Conduction

Table 2.1 lists the typical durations of ECG features. These durations formed the basis of the timing cycles used in the software (see Chapter 7).

Table 2.1 Typical Duration of ECG features.

Feature	Duration (msec)
QRS complex	70-110
R-R interval	600 to 1000
P-R interval	150 to 200
S-T interval	320

For reference purposes all ECG definitions are shown on figure 2.3.

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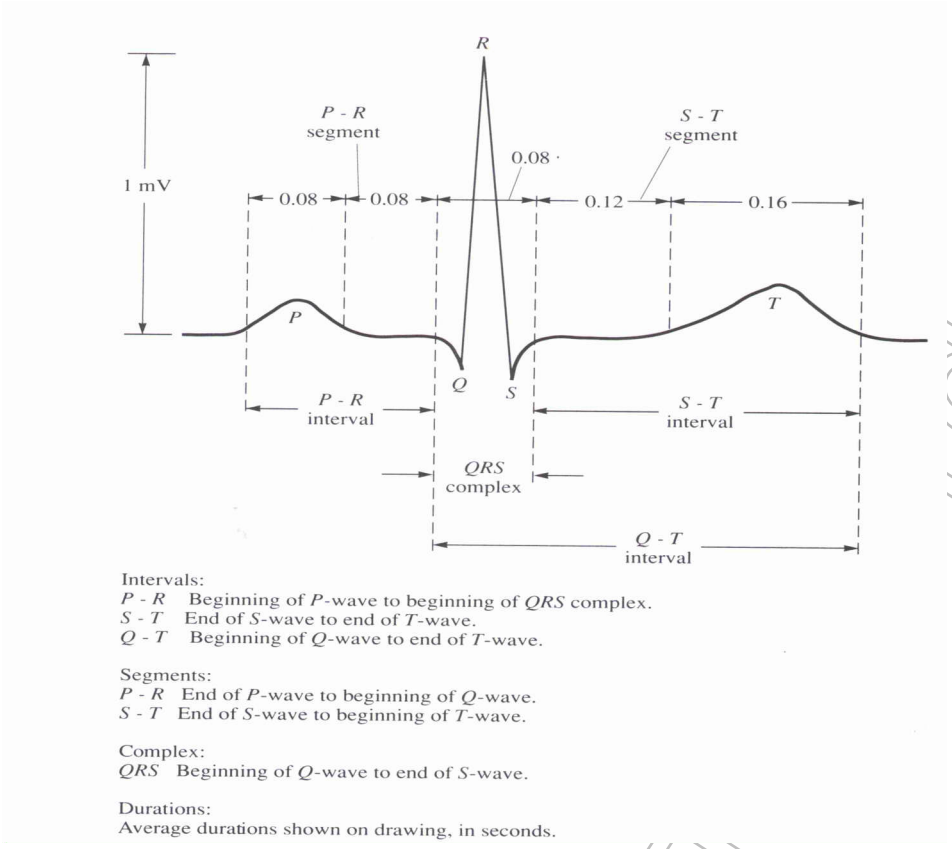

Figure 2.3: ECG definitions. Source Aston[1].

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Chapter 3 Pacemakers

In this chapter the physiologic conditions under which pacing is indicated are presented, together with the different types of pacemakers.

Most of the discussion is taken from lecture notes prepared by Mr Tony Compton for the Medical Electronics course[2], and by the Webster encyclopaedia[3].

3.1 Indications for Pacing

In chapter 2 it was shown that the rhythm of a healthy heart is determined by spontaneous pulses generated by the sino-atrial (SA) node. Signals from the SA node spread through the atria causing them to contract, are delayed in the atrio-ventricular (AV) node, conveyed rapidly through the His-Purkinje fibres and finally activate the ventricular muscle.

3.1.1 Disorders of Impulse Conduction: Conduction Delay and AV Block

If any part of the impulse conduction path is faulty (see Figure 2.2), the condition of **heart block** occurs. This occurs in several degrees of severity. The most usual dysfunction of this path happens on the bundle of His.

1st Degree Block : The conduction path has excessive delay so ventricular depolarisation is late. This can cause faintness during exercise as the ventricles may not have time to fill properly during diastole, but the condition often shows no symptoms. Usually a pacemaker is not needed.

ECG characteristics: Each P-wave is conducted, but the P-R interval exceeds 0.2 sec and remains constant. Rhythm is regular and QRS is normal.

2nd Degree Block : The conduction path is bad enough to cause occasional signals to be too weak to fire the ventricles. The ventricles will eventually fire spontaneously but the beat will be very late and progress through the heart from apex to base, causing an inverting ECG waveform. If the late and slow beats occur frequently, the condition causes temporary weakness and breathlessness and a pacemaker may be prescribed.

ECG characteristics: At regular or irregular intervals, a P-wave is not followed by a QRS complex. The P-P interval is constant.

Two types of 2^o degree block can be found.

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The less serious **Mobitz type I**, where succeeding P-R intervals are gradually prolonged until conduction fails and the node "recovers" with a shorter conduction time. This type is generally transient and treatment is seldom indicated.

A more serious type is the **Mobitz type II** in which random atrial impulses fail to conduct. This type is an indication that complete heart block might occur sometime later on. It results from degenerative diseases in the conduction system. Pacemaker is indicated.

3rd Degree Block (total block): The conduction path has failed completely and the ventricles beat at a slow rate which is independent of the SA node and therefore also of any increased demand because of exercise. The sufferer experiences weakness and may occasionally lose conciousness (Stokes-Adams attack). Before the advent of pacemakers the prognosis was a 50% possibility of survival for one year from the first attack.
ECG characteristics: This rhythm indicates a complete lack of conduction between the atria and the ventricles. Atrial rhythm is regular, ventricular rhythm is regular but slower than the atrial rate. P-waves bear no relationship to QRS complexes. The QRS complex can be narrow or wide depending on the site that takes over the pacemaker function.

3.1.2 Disorders of Impulse Formation: Sick Sinus Syndrome

A second group of conditions that lead to the prescription of pacemakers are dysfunctions of the sinus node. The AV conduction is satisfactory, but the atrial rate is too slow (**sinus bradycardia**), or widely variable. While not fatal, it degrades the patient's quality of life.

3.1.3 Ventricular Tachycardia

Ventricular tachycardias are life threatening in themselves and can lead into fatal ventricular fibrillation. Treatment requires cardioversion. However, patients may not be within reach of one all the time. Pacemaker pulses, properly timed, can break up such a tachycardia. However such treatment can also elicit fibrillation.

3.1.4 Ventricular Fibrillation

Fibrillation is the uncoordinated and uncontrolled beating of small muscle groups of the heart each trying to pump blood on its own. The heart pumps no blood. The condition is usually fatal unless promptly treated with a defibrillator. Cardioverter/defibrillator functions can be incorporated into a pacemaker. More usually it is vice versa.

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3.2 The pacemaker

A pacemaker is an electronic device which stimulates the heart when it would otherwise beat too slowly. It consists of a small package containing the power source and control electronics and a lead which conveys stimulation pulses to the heart and monitoring signals from it. The package is placed in the body outside the ribs. The lead is pushed along an arm vein into the ventricle (in the case of VVI pacemakers).

For the pacing pulse a voltage of around 5 V is required with a pulse duration of 0.5 msec.

3.2.1 VVI pacemakers

The first implantable pacemakers simply fired a 2 msec pulse into the heart. The trend from there onwards is towards controlling the pacemaker rate and function.

For patients who have near-normal heart function and only occasionally experience a syncope, a fixed rate pacemaker would compete against their own rhythm most of the time. Worse a pacing pulse might fall into the T-wave. This could initiate tachycardia or even fibrillation.

A **triggered** circuit waits for a natural beat, sensed electronically. If it fails to appear after a set time, an artificial pacing pulse is output; if a natural beat appears, the device fires a pulse at the same time. Triggered mode has the advantage that if the conduction path is only partly working it can boost it with its added pulse. Also, in the presence of interference it will continue to fire, whereas an inhibited mode device could stop. It must contain a refractory period after the pacing pulse to ensure interference does not cause an "R-on-T" pulse, with its attendant danger of fibrillation.

Inhibited-mode pacemakers function only when sensing that the heart is not contracting. They are inhibited by the presence of an R-wave. They count out a specified elapsed time interval following the R-wave. In the case of VVI pacemakers if no R-wave appears before they time out, a pulse is released to stimulate the ventricles. If an R-wave did appear during countdown, the interval counter is reset. The VVI pacemaker ensures a heartbeat no slower than its set rate.

Inhibited mode has the great merit that, for many heart conditions, it is only drawing current for the small fraction of the time that the heart's own rhythm is disturbed. For this reason, inhibited mode is preferred, with care taken to keep the effects of external interference to a minimum.

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After a pulse has been generated the pacemaker enters an insensitive period (refractory period). This is to ensure that no inappropriate signal is interpreted as an R-wave. The refractory period for ventricle sensed pacemakers is 250-400 msec.

The definition NASPE/BPEG[4] gives for a VVI pacemaker is the following: "Inhibited ventricular pacing; pacemaker stimuli occur at the escape interval in the absence of spontaneous sensed events. In the presence of a spontaneous event, provided it occurs after the pacemaker refractory period, the pacing stimulus output is inhibited and the next pacing cycle interval begins to time out".

The behaviour of a VVI pacemaker is independent of atrial activity. Ventricular contractions are synchronous with atrial ones, to ensure an appropriate degree of filling. The VVI pacemaker will often capture the ventricle before it has been able to fill adequately with blood . As a result cardiac output will fall (by as much as 15%). This is called "pacemaker syndrome". It would be better for these cases to have a slower unpaced rhythm with satisfactory cardiac output.

3.3 Modalities

A large number of different pacemaker configurations are possible to suit individual problems. Either the atrium or the ventricle or both may be paced and the same applies to any sensing for synchronisation. In addition there are different responses to natural beats along with programming and communications options. Table 3.1 shows a classifcation system as adopted by NASPE/BPEG.

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Table 3.1: NASPE/BPEG Generic Pacemaker Code

Position	I	II	III	IV	V
Category	Chamber(s) paced	Chamber(s) sensed	Response to sensing	Programmability, rate modulation	Antitachy-arrythmia functions
	0 = none	0 = none	0 = none	0 = none	0 = none
	A = Atrium	A = Atrium	T = Triggered	P = Simple Prog	P = Pacing (anti-tachy)
	V = Ventricle	V = Ventricle	I = Inhibited	M = Multi-prog	S =Shock
	D = Dual (A+V)	D = Dual (A+V)	D = Dual (T+I)	C = Communication	D = Dual (P+S)
				R = Rate Modulation	

The choice of chambers to pace or sense depends on the individual pathology, 2nd degree block might be dealt just by ventricular pacing while a heart suffering total block might need both chambers to be based and sensed.

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Chapter 4 The Heart Simulator

The Laerdal Heartsim 2000 is an ECG and Haemodynamic waveform simulator. Only the ECG simulator is used. It is designed for realistic simulations in teaching arrythmia recognition and defibrillation/cardioversion. The Heartsim 2000 consists of a central unit with a remote control keyboard. It comes with an extensive ECG library. There are 8 types of QRS complexes (see Table 4.1) and 14 basic rhythms (see Table 4.2).

The operator can increase or decrease the pulse rate, introduce premature complexes , and add interference of house current (60 Hz) or muscular artefacts.

The premature complex types available are

- Unifocal premature ventricular complexes
- Multifocal premature ventricular complexes
- Couplet premature ventricular complexes
- Premature atrial complexes
- Premature junctional (nodal) complexes

For definitions of the basic rhythms and premature complexes please refer to Appendix 1.

Table 4.1 Description of supraventricular QRS types available

QRS Type	Description (for pictures look appendix X)
A	Normal upright QRS-T
B	Upright QRS with ST depression and T inversion
C	Upright QRS with ST elevation
D	Bundle Branch Block: broad R wave with T inversion
	BiPhasic QRS with T inversion
F	QS with ST elevation
G	Bundle Branch Block: broad S wave with upright T wave

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Table 4.2 Basic rhythms and their rate range

Basic Rhythms	Rate
Normal Sinus Rhythm, Sinus Bradycardia, Sinus Tachycardia	30 - 170
Atrial Tachycardia	90 - 260
Atrial Fluttering	75 - 150
Atrial Fibrillation	40 - 180
Junctional (Nodal) Rhythm	30 -180
Idioventricular	35 - 75
Ventricular Tachycardia	120 - 210
Ventricular Fibrillation	Very coarse - Very Fine
Asystole	-
1^0 Atrio-Ventricular Block	40 - 85
2^0 Atrio-Ventricular Block Type 1	60 - 110
2^0 Atrio-Ventricular Block Type 2	60 - 110
3^0 Atrio-Ventricular Block	30 - 50

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Chapter 5 DSP Board and Development tools

This chapter presents the features of the DSP starter kit which includes software and hardware. It was used as the processing unit of the ECG signal. The code name of the package is TMS320C6211 DSP Starter Kit, produced by Texas Instruments and operating at 150 MHz. Its components, capabilities and limitations will be presented in relation to the work done and as information for any further work.

5.1 Introducing the TMS320C6211 (‘C6211).

The ‘C6211 is a low-cost version of the original ‘C6000 device, the ‘C6201. The ‘C6211 device provides 1200 MIPS (million instructions per second) at 150 MHz. Fixed-point device. It is based on very long instruction word (VLIW) architecture, with flexibility to overcome problems of early VLIW designs. That helps to have increased instruction-level parallelism.

It has eight execution units. These units operate in parallel. They can perform up to eight instructions during a single clock cycle.

On chip peripherals include:

- External Memory Interface. Can interface to 8-, 16-, and 32- bit SDRAM, and asynchronous memories.
- Multi-Channel Buffered Serial Ports (McBSPs). One of them is used in the project. Serial Peripheral Interface (SPI) compatible.
- Host Peripheral Interface. 16-bit asynchronous.
- Two 32-bit Timers. None of them is used.
- Interrupt Selection. McBSP1 Receive interrupt is used. There are other 15 hardware interrupts to use.

The ‘C6211 is a cache based device. On-chip cache provides a 98% hit rate. The cache architecture allows for the low cost of the device. Saves up by using slow, less expensive memory.

On-chip memory consists of 72 Kbytes. 8 Kbytes serving as level 1 cache that CPU can directly access. Of that 4 Kbytes are used for program and 4 Kbytes for data. The data path to the CPU allows for eight 32-bit instructions during every cycle. The cache uses a

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least-recently-used replacement scheme. The remaining 64 Kbytes of on-chip memory can be used as level 2 cache, or be directly mapped as internal memory (RAM).

5.2 ‘C6211 Contents

Hardware included

- 'C6211 DSK Board - Easily connects to a PC through a parallel port cable (included): 150 MHZ 'C6211 DSP (see Figure 6.1)
- 4 MB External SDRAM and 128 KB External Flash - Provides additional program and data storage
- TI'S TLC320AD535 16-bit Data Converter
- TI'S TPS56100 Power Management Device
- JTAG Controller - Provides easy emulation and debugging
- Expansion Daughter Card Interface - Provides extensible system development
- CE-Compliant Universal Power Supply DSK

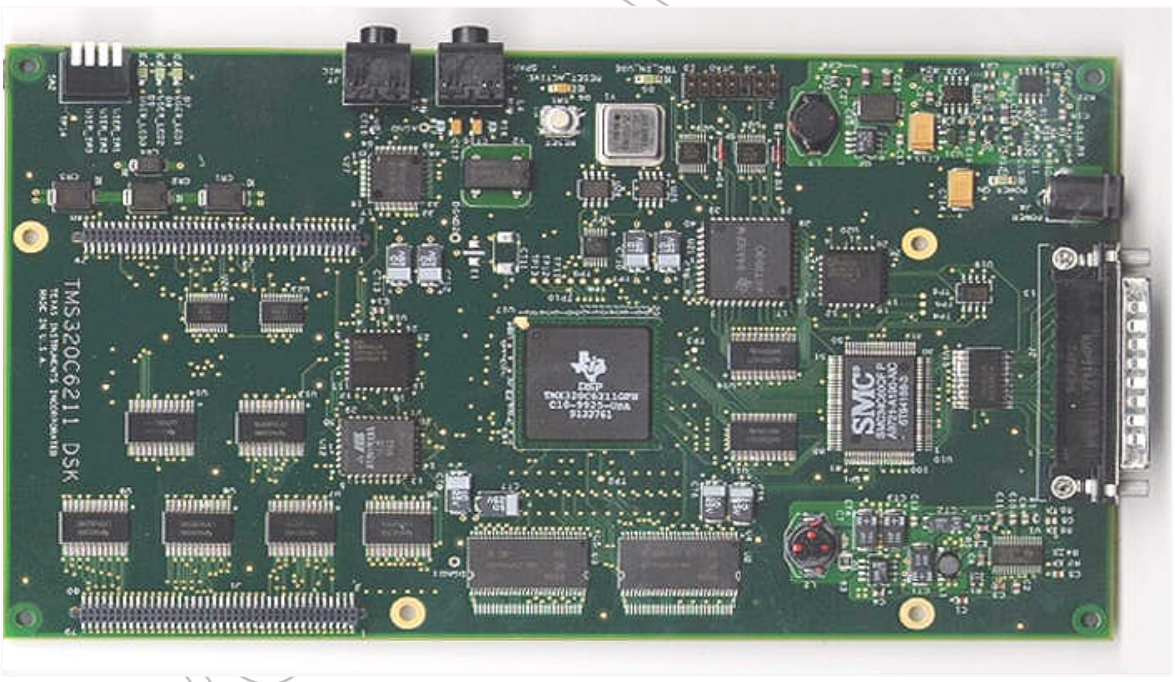

Figure 5.1 ‘C6211 DSP board.

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Software Included

- 'C6000 C Compiler and Assembly Optimizer
- Code Composer Debugger
- DSK support software
    - Flash utility
    - Sample programs (including the ‘audio’ example used in this project)
    - Confidence tests

5.3 Code Composer Studio

Code Composer Studio (CCS) allows the developer to create, build, test and debug programs. The program must be built, loaded and then run. Before loading the DSP must reset. In the build options window there are Compiler, Assembler and Linker tabs. There are various commands for each of these fields. Full optimisation, on the compiler, makes the program more efficient. Not optimised code runs slower than optimised code.

When developing and testing programs it is often needed to check the value of a variable during execution. Breakpoints and the Watch window can be used. Use the step command to access instructions after the breakpoint. Functions can be stepped over or can be stepped into for detail. Structures can be monitored on the watch window, by expanding the structure name in the window. CCS also offers code profiling features to gather statistics about the execution of any part of the program. The profiling clock counts instruction cycles. Profile points report the number of instruction cycles since the previous profile-point or since the program started running. On the profiling statistics window the feature that is most important is the minimum number of cycles. Graphs can be added to view the signal in time or frequency domain. This option comes handy when using digital filters. Animation of code is also on offer if needed. During animation a coloured line over the statement highlighted switches on and off as the program executes that statement. All the above mentioned features while helpful in debugging the code they consume many cycles to execute. When it is decided that the program is bug-free these features should be switched-off. Otherwise data might be lost especially when using I/O.

CCS also offers the DSP/BIOS tools. These include the statistics windows used with the profiling points. The execution graph shows in real time the execution of all processes and threads in the program. How many clock cycles each process consumes and if there is

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any conflict between the processes it can be seen from the execution graph. Processes can be hardware interrupts, software interrupts or periodic objects. All processes can be set up graphically and relatively easy. Another useful feature is the CPU load graph. The execution graph and the CPU load graph are shown in figure 5.2. The only software interrupt in the program is the "audioSWI". The CPU with the full program up and running is loaded only 3%.

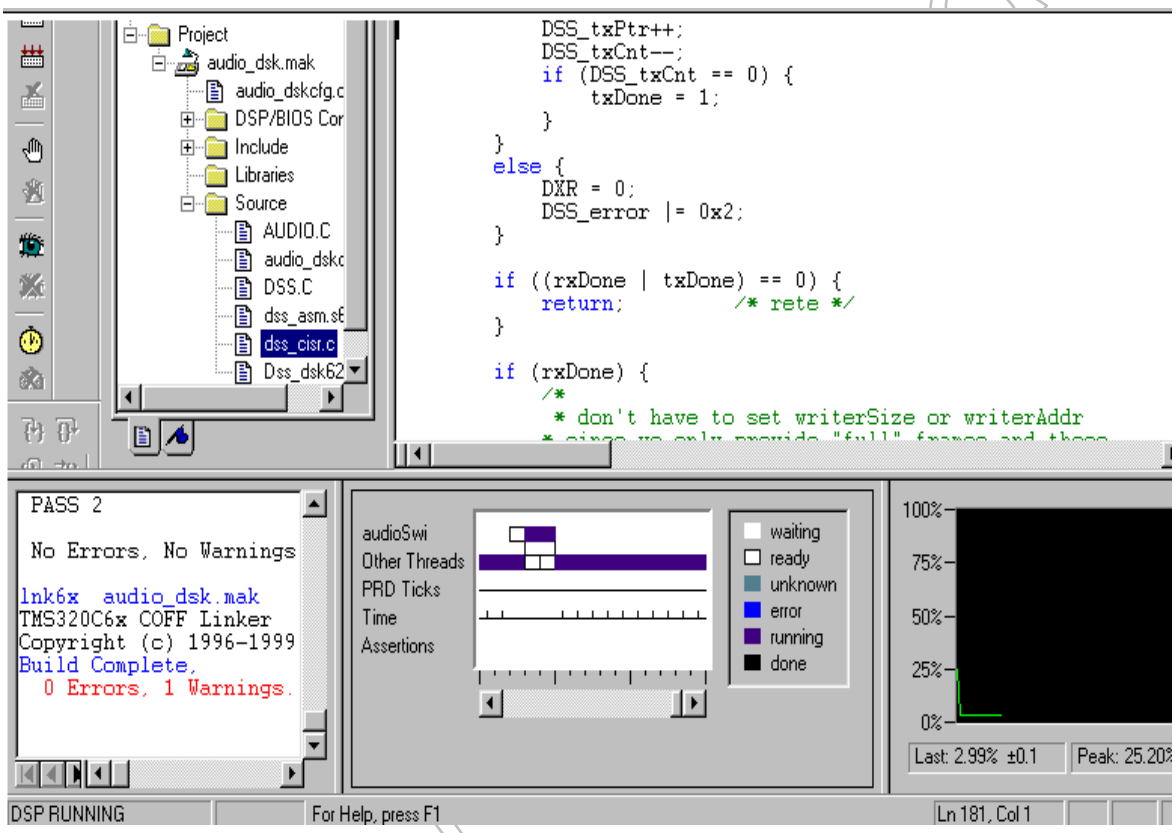

Figure 5.2 The Code Composer Studio environment

5.4 Evaluation of 'C6211 in relation to the objectives of the project

The 'C6211 is designed with telecom applications in mind, such as ADSL, multi-channel modems, and GSM vocoders. Its advantage is that it can perform high-speed number crunching routines in real time, while relying in inexpensive external memory for program and data storage. For a pacemaker design, external memory should be avoided if possible due to power consumption and extra bulk. The designer should concentrate on utilising the 72 Kbytes of on-chip memory of which only 4kbytes are available for program memory. Assembly programming for greater efficiency is needed. If monitoring capabilities are required the remaining 64 kbytes can be configured as RAM allowing electrogram records of

approximately 4-min duration, which is about the state of the art today. Actual duration will depend on sampling rate and compression techniques. As for "higher speed number crunching in real time" it would only come of use if dealing with arrythmia recognition algorithms with high computing needs. Such algorithms might be the time domain morphology analysis Probability Density Function (PDF)[5] or the Gradient Pattern Detection (GDP)[6]. Correlation Waveform Analysis[7] is also known to make heavy demands on computation. These methods can be used with slower machines which might have very limited memory by being invoked only when there is a possibility of arrhythmia[8]. For simple pacemaker designs such a VVI design a general-purpose microprocessor should be more than enough. Overall, DSP's are not needed for pacemaker only algorithms.

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Chapter 6 Biopotential Amplifier

The purpose of this chapter is to introduce the amplifier which was designed and built for amplifying the ECG signal. Why it was needed, what are its requirements, how they were met, schematic diagrams and output graphs are all to be found in this chapter.

6.1 General Specifications

The ECG signal represents the sum of the electrical potentials of all the depolarising tissue of the heart. Real practice ECG measurements (and the output of the Heartsim 2000) involve voltages around **2mV**, with **high source impedance** and (as an option on Heartsim 2000) superimposed high-level **interference** signals and **noise**.

The signal needs to be amplified to utilise the full range of the A/D converter, which is included in the DSP board.

The amplifier must be adequate to measure the signal.

It has to provide **amplification selective** to the ECG signal and reject everything else.

6.2 Basic Requirements

Two basic requirements apply in our case.

- The amplifier should not distort the measured signal.
- The amplifier should provide the best possible separation of signal and interferences.

Three electrodes, two of them picking up the biologic signal (RA,LA) and the third (RL) providing the reference potential make up the connection of the human subject to the amplifier. These connections are the outputs at the rear of the Heartsim 2000. The input signal to the amplifier consists of the desired biopotential, power line interference of 60 Hz, and its harmonics, and noise. In addition to these elements the Heartsim gives the chance to experience simulated muscle noise and even more power-line interference. Proper design of the amplifier rejected a large portion of these interferences.

The differential amplifier has a central role in our design. The main task is to reject interference coupled into the signal. The ECG appears as a voltage between the two input terminals (**differential signal**).

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The line frequency interference signal causes approximately the same potential at both inputs (**common-mode signal**). Strong rejection of the common mode signal is one of the most important characteristics of a good biopotential amplifier. The common mode rejection ratio (**CMRR**) of an amplifier is defined as the ratio of the differential mode gain. The CMRR of the TL071 op-amp is **86 dB** (typical)[9].

The rejection of the common-mode signal in a biopotential amplifier is a function of both the amplifier CMRR and the source impedances. Source impedances ideally should be equal. If they are not, the common mode voltage drop shows a differential signal at the amplifier input (unwanted). In practice equal resistors do not exist, and for sufficient rejection of interference, a minimum CMRR of 100 dB is needed[10] and an input impedance (of the amplifier itself) of at least 10^9 Ω to prevent source impedance imbalances from deteriorating the overall performance.

As stated above, the CMRR of the op-amps used is 86 dB, lower than what in theory is needed. But, because this project is not real practice, though it has a real budget, the 86 dB of the £0.30 TL071 were considered enough for the purpose of the project. The results also justify the choice. TL071 **input impedance is 10^{12} Ω** [9], a magnitude of a 1000 more than theory states as optimum.

In addition to electromagnetic interference, noise generated by the amplifier and the connection between the source and the amplifier has to be taken into account. High signal-to-noise ratios require the use of very low noise components. Very **low noise** (**15 nV√Hz** [9]) op-amps were used to reduce the noise inherent in the amplifier.

The purpose of the high-pass and low-pass filters is to eliminate interference signals, like amplifier offset potentials (around 0.5V in our case) and to reduce the noise amplitude by the limitation of the amplifier bandwidth.

Based on the ECG signal parameters (amplitude of around 2 mV, bandwidth of 1-100 Hz) **amplification factor of 200**, and a **bandwidth of ~30 Hz** (9-40) was chosen. The highest frequency in the ECG signal is contained in the R-wave and is 10-30 Hz[11]. For diagnostic, experimental or clinical applications the bandwidths employed differ and are somewhat larger than the 30 Hz employed here. The T wave contains no necessary information for the pacemaker. Its frequency is approximately 5 Hz or less[11]. The lower cut-off frequency of the amplifier is 9 Hz and most of the T wave energy is cut off.

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6.3 The Amplifier

The ECG amplifier design is shown in Figure 5.1. It consists of three stages. The pre-amplifier (op-amps 1 and 2), the instrumentation amplifier (op-amps 3-5) and the bandpass filter (op-amps 6 and 7).

The bandpass filter is needed to cut-off frequencies outside the useful ECG bandwidth and to reduce the effect of aliasing induced by sampling. Without filtering the 50 Hz mains noise (or other noise) could replicate itself in the signal band corrupting the information. It is a second order Bessel roll off. Its cut-off frequencies are shown on equations (6.1) and (6.2).

Lower cut-off frequency: $f_{lc} = \frac{1}{2\pi RC} = \frac{1}{2\pi \times 220\times10^{-9}\times82\times10^{3}} = 8.82 \text{ Hz}$ (6.1)

Upper cut-off frequency: $f_{uc} = \frac{1}{2\pi RC} = \frac{1}{2\pi \times 150\times10^{-9}\times27\times10^{3}} = 39.2 \text{ Hz}$ (6.2)

The main task of the instrumentation amplifier is to sense the voltage between the measuring electrodes (RA,LA) while rejecting the common mode signal. Such a differential amplifier cannot be realized using a single op-amp design, since this does not provide the necessary high input impedance. The general solution to the problem involves voltage followers to attain high input impedances.

The two input op-amps (3 and 4 in figure 5.1) provide high differential gain and unity common-mode gain without the requirement of close resistor matching. The differential output from the first stage represents a signal with substantial relative reduction of the common-mode signal and is used to drive a standard differential amplifier which further reduces the common-mode signal. The gain of the instrumentation amplifier is shown in equation (6.3).

$$Av = \left(\left(\frac{2\times R2}{R1}\right)+1\right)\times\left(\frac{R5}{R4}\right) = \left(\left(\frac{2\times68\times10^{3}}{680}\right)+1\right)\times\left(\frac{10\times10^{3}}{10\times10^{3}}\right) = 200 \quad (6.3)$$

The pre-amplifier provides additional gain due to the very low level of the ECG signal.

The pre-amplifier stage is badly placed before the instrumentation amplifier. It cancels the advantage of high input impedance. Any further amplification to the signal should be provided after the instrumentation amplifier. In the context of the project it did not make much difference to the signal. It was placed there in order to avoid having to built the amplifier from scratch. The instrumentation amplifier and the filter had been built before realising that further amplification was needed. It is bad practice and should be avoided.

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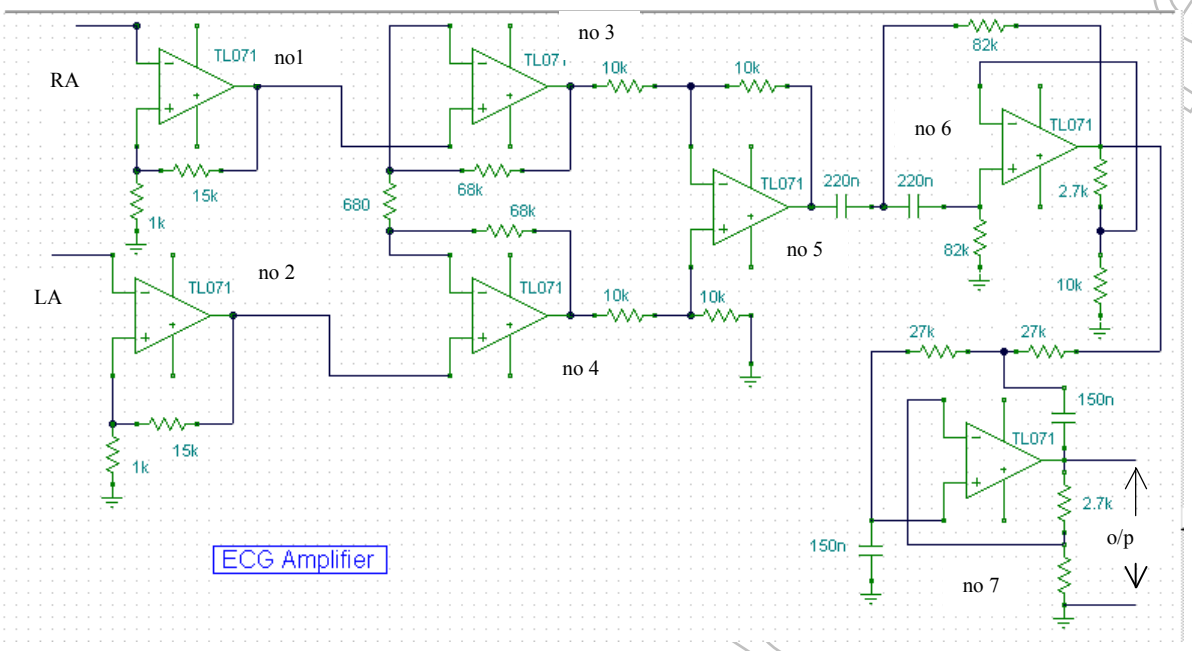

Figure 5.1: ECG Amplifier. Schematic diagram produced using "TINA" drawing package.

Figure 5.2 shows a graph of the ECG signal with no amplification, as it was coming out of the Heartsim.

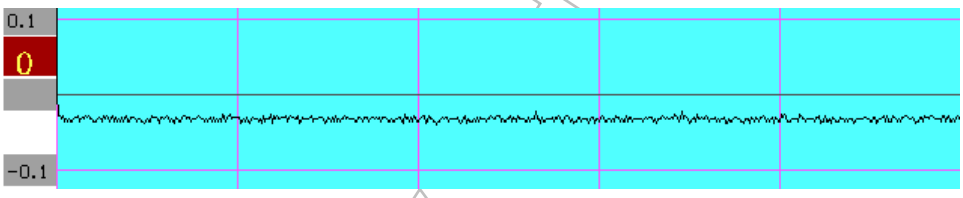

Figure 5.2 Heartsim output with no amplification

Figure 5.3 shows an amplified version of the ECG signal, from the amplifier of Figure 5.1. The only difference is that Figure 5.2 was amplified with a lower cut-off frequency of 2 Hz and all the T wave energy has been preserved. The effect of saturation is evident on the QRS wave.

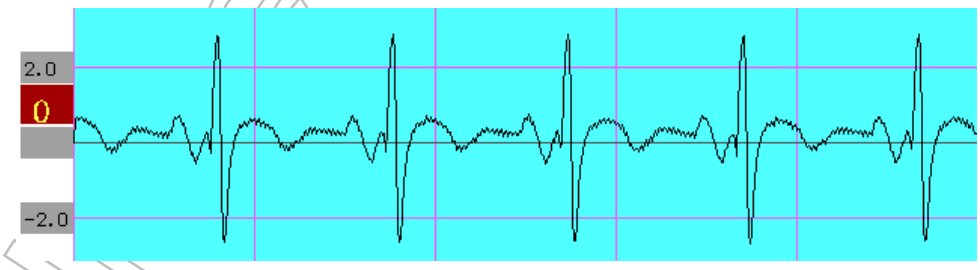

Figure 5.3 Amplified ECG signal. QRS Type A, rate 80.

Chapter 7 Software for Pacing

-Key Points

- Sample the ADC at Regular Intervals
- Peak Detection
- Measuring Interval in Between Peaks
- Respond to changes in the rate of change of heart rate
- "Blind Time" after QRS detection

7.1 Requirements of the system

The pacemaker's function is essentially a "hard" real-time task, in that it must respond to cardiac events within strict deadlines. Therefore, such a system that has a very strict response time and must not be allowed under any circumstances to "crash" because the consequences are life threatening.

Cardiac events happen at relatively long intervals, compared with other non-medical applications that DSPs and software has being written for.

The system must continuously receive data from the heart and in our case it must also continuously transmit data so as to observe its response together with the events. This is not the case in real time pacemakers. The system only outputs data when necessary.

The highest frequency in the ECG signal is about 30 Hz and is contained on the R wave. According to the sampling theorem any continuous-time signal must be sampled at least at twice its highest frequency so that it can be completely recovered from its samples. The R-wave is rapidly changing and its amplitude is very important in determining whether a pulse has occurred. It is best practice to be sampled at least five times its highest frequency, at 150 Hz, so the R-wave amplitude is not undersampled and important information is lost.

7.2 Utilising an example program

The following discussion describes the operation of the "audio" example, which was included in the DSP package. It can be found in detail in document "SPRA598 An Audio Example Using DSP/BIOS" from the official Texas Instruments website www.ti.com [12]. The software that was written for the purpose of the project is presented after this discussion, not to cause confusion of what was done and what was already written.

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The “audio” example explained next suits the application as it is desired to continuously sample and process data. The audio example was used to move data from the ADC to the serial port, and from there to a software interrupt function and back again to the serial port connected to the ADC.

The aim of the example is to use the DSP/BIOS(TI™) kernel for scheduling data transfer between the hardware I/O peripherals (ADC) and the DSP. In short, for managing data transfer.

The DSP/BIOS **pipes** or “PIP” module was used to buffer streams of program input and output data. They manage I/O in blocks (also called stream-based or asynchronous I/O). Each pipe buffer is divided into a number of frames. The pipe has two ends, the writer and the reader. Data notification functions are performed to synchronise data transfer. One end of the pipe is controlled by the hardware ISR (serial port receiver ISR) and the other end is controlled by the software interrupt function.

Data input from the codec flows from the serial port ISR through the receiver pipe (DSS_rxPipe) to the software interrupt, where it is copied to the transmitter output (DSS_txPipe) and sent back to the serial port to be transmitted through the codec. It is on the bit of the ISR that writes the sample value to the Data Transmit Register, that intervention was made to modify the data so as to monitor and control the output at our will.

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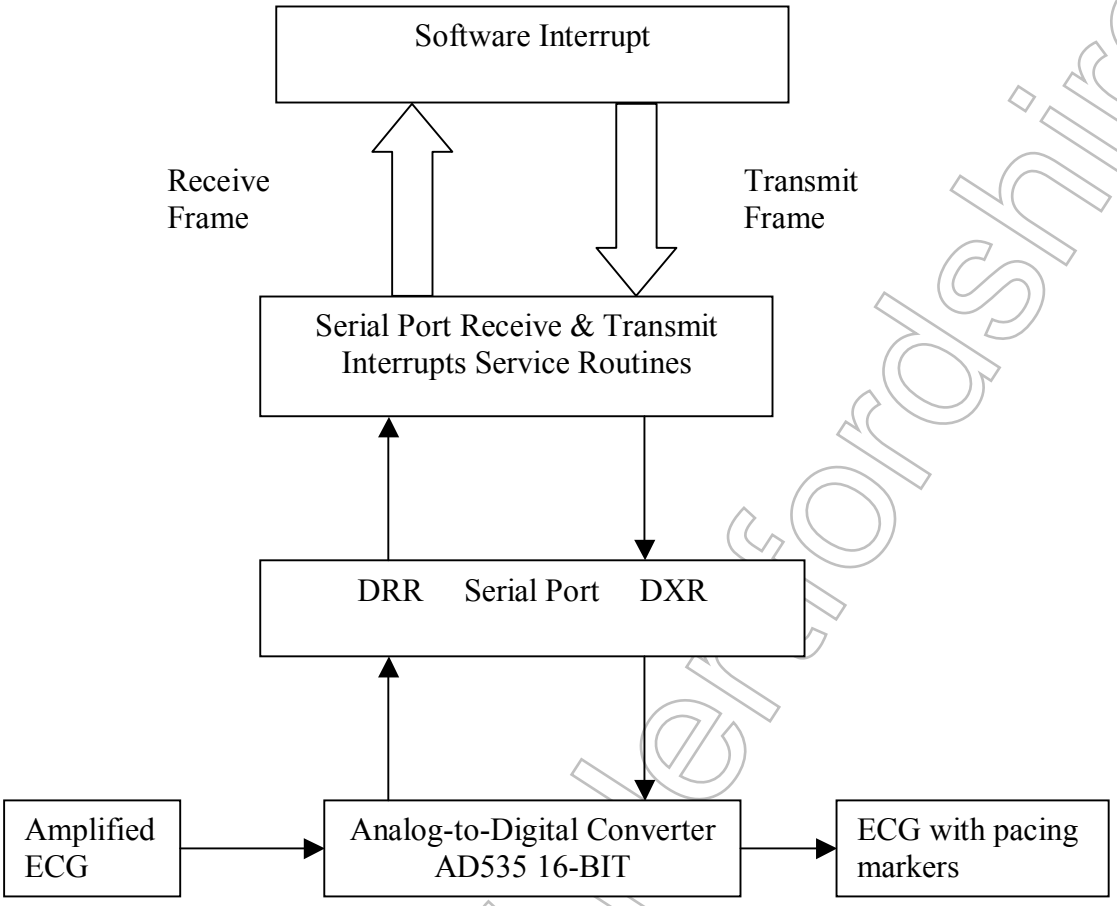

Figure 7.1. Data path flow within the DSP board

The ISR for the serial port receive interrupt (Appendix 3, source file dss_cisr) copies each new 32-bit data sample in the Data Receive Register (DRR) (Appendix 3, source file dss_dsk6211.c) to a frame of the DSS_rxPipe (Appendix 3, source file dss.c). When the frame is full, the program puts the frame back into DSS_rxPipe to be read by the audio function (Appendix 3, source file audio.c).

As the audio function will just read a frame and copy it, the transmit rate will be the same as the receive rate: 48 kHz. That is why only the receive interrupt for the serial port was enabled. The transmit interrupt for the serial port is not enabled. The program was later changed to include the required extra processing to fulfil the objectives of the project. It was decided to continue with the above principle as it did not cause any delays or distortion to the output data. The 48 kHz sampling rate employed here is not the rate at which real-world pacemakers are used. That is because of the limited data area (higher sampling rate means more samples to store), and restrictions on power consumption that implantable devices have to operate. The quantisation of the ADC IS 16-bit and cannot be changed.

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The sample rate could be imitated to be lower by not executing the ISR every time it is called. The least sampling rate that the 'C6211 can get down to is 22 kHz. Because the project did not deal with real implantable devices it did not employ any of the above measures but the difference must be mentioned.

One way not to execute the ISR every time it is called is shown in Figure 7.2.

```
int GLOBAL_VARIABLE = 0;

void ISR(void){
GLOBAL_VARIABLE +=1;
if (GLOBAL_VARIABLE == DELAY){
        execute isr statements
        GLOBAL_VARIABLE = 0;
        }
}
```

Figure 7.2 Virtual Slower Sampling Rate

7.3 The Pacing Algorithm

7.3.1 The Threshold Stimulation

Only the QRS complex is of interest for a VVI pacemaker so the ECG signal was stripped out of everything by using a threshold level. "The threshold stimulation is defined as the minimum amplitude and stimulus duration that consistently results in cardiac depolarisation outside the physiologic refractory period"[13]. From the definition it is evident that three parameters in a pacemaker design should be taken into account when detecting the minimum threshold of stimulation. The minimum amplitude, the stimulus duration and the refractory period.

The minimum amplitude is used to define if an input sample is part of a heartbeat or not. This is a sample by sample approach. No consideration about pulse duration is made at this point. The pulse is recognised at its onset. This is an idealistic approach. In real world data capturing apparatus pulse amplitude may vary due to physiological and/or instrumentation reasons. Because of that both the amplitude and its duration are needed to testify a pulse. However, the output from Heartsim has a constant QRS amplitude. Thus, with certainty minimum amplitude can be predetermined and set at the right level.

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The system needs to be safeguarded against pulses happening at the refractory period and recognising them as ventricular depolarisation. Such pulses are not taken into account when calculating the escape interval. For the escape interval to be updated it needs both a sample above threshold and some time (0.2 sec) to have passed since the last onset detection. Samples above minimum threshold happening within the 0.2 sec time after the onset will appear at the output but they will not trigger an interval update. Such samples might be the rest of the QRS pulse and maybe some false detected action potentials. The stimulus duration and the refractory period are folded into one block of time.

7.3.2 Pacing Decision

If the input sample is below threshold (not a natural pulse) and there is no pacing taking place at that moment the output is set to zero. After that there is no updating of the escape interval. The program reaches the point where it is to decide if a pacing pulse should fire or not. It evaluates two conditions. The first tests if the global time has exceeded the escape interval. Global time is incremented by one every time the ISR is entered. It resets whenever there is a new heartbeat. The escape interval used is the most recent one updated.

The second condition is the "wait" variable evaluated against the escape interval. The "wait" variable is incremented by one each time the ISR is entered. Its difference with global time is that it resets when the pacing pulse duration expires.

If the two above conditions are true the output is set to the pacing pulse amplitude. After that the pacing pulse duration is incremented.

The last "if" statement is dealing with the termination of the pacing pulse. If the pacing pulse duration has reached its predetermined limit (0.1 sec) the pacing pulse stops. Its duration variable resets as well as the "wait" variable. The global time is not reset.

If on the next calls to the ISR there is not a heartbeat detected the wait signal ensures that the next pacing pulse will happen only when the most recent escape interval is exceeded again. Pacing pulses do not last indefinitely because of the "wait" variable.

7.3.3 Updating the Escape Interval

The parameter that is taken in to account for deciding if it is appropriate to pace is the **time difference between QRS complexes**. To measure time differences, a clock is needed. The internal programmable clocks could be used for this purpose but in order to minimise CPU load in setting up and running the clocks, a simpler approach was taken. The ISR was

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used as an indicative clock. It occurs at regular intervals and has the highest priority. With the utilisation of global variables, numerical values were saved in between the calls to the ISR. Time is measured as number of calls to the ISR. 500 calls equal 0.1 sec, 5000 calls equal 1 sec.

When the program recognises a heartbeat that does not happen within the refractory period it is given the green light to update the new average escape interval. The last three intervals are averaged. One of them each time is updated. A hysteresis period is added to the detected average value to accommodate for normal heart rate variability. This is set to plus ten percent.

The detected escape interval is then compared to two limits. If the average interval exceeds any of those limits the interval is set at a predetermined value of 1 sec. If it is within the limits its value is the one that was calculated.

The long interval limit (1.2 sec) purpose is to set a maximum waiting interval. Thus if the detected average beat interval exceeds 1.2 sec then the program should not assign the calculated value to the escape interval. It is evident that the heart is experiencing a serious problem. The predetermined interval is set (1 sec). It is short enough to illicit a pacing pulse. Hence a hard limit is established. Heartbeats occurring in longer than the hard limit intervals will activate pacing pulses. Also when there is no ventricular contraction at all the pacemaker will be active in its default rate (1 sec).

Detected average intervals that breach the short interval limit (0.8 sec)indicate that the heart rate is high enough not to need constant supervision. Thus, the “average waiting interval” is set at the predetermined rate which is much longer. If a short limit was not in place the program would follow a heart rate of say 100 bpm and when it slowed down say below 90 bpm it would start firing a pacing pulse, which is undesirable.

In detected average intervals that are within the limits the escape interval essentially traces the heart rate. The program is like being in an alert state.

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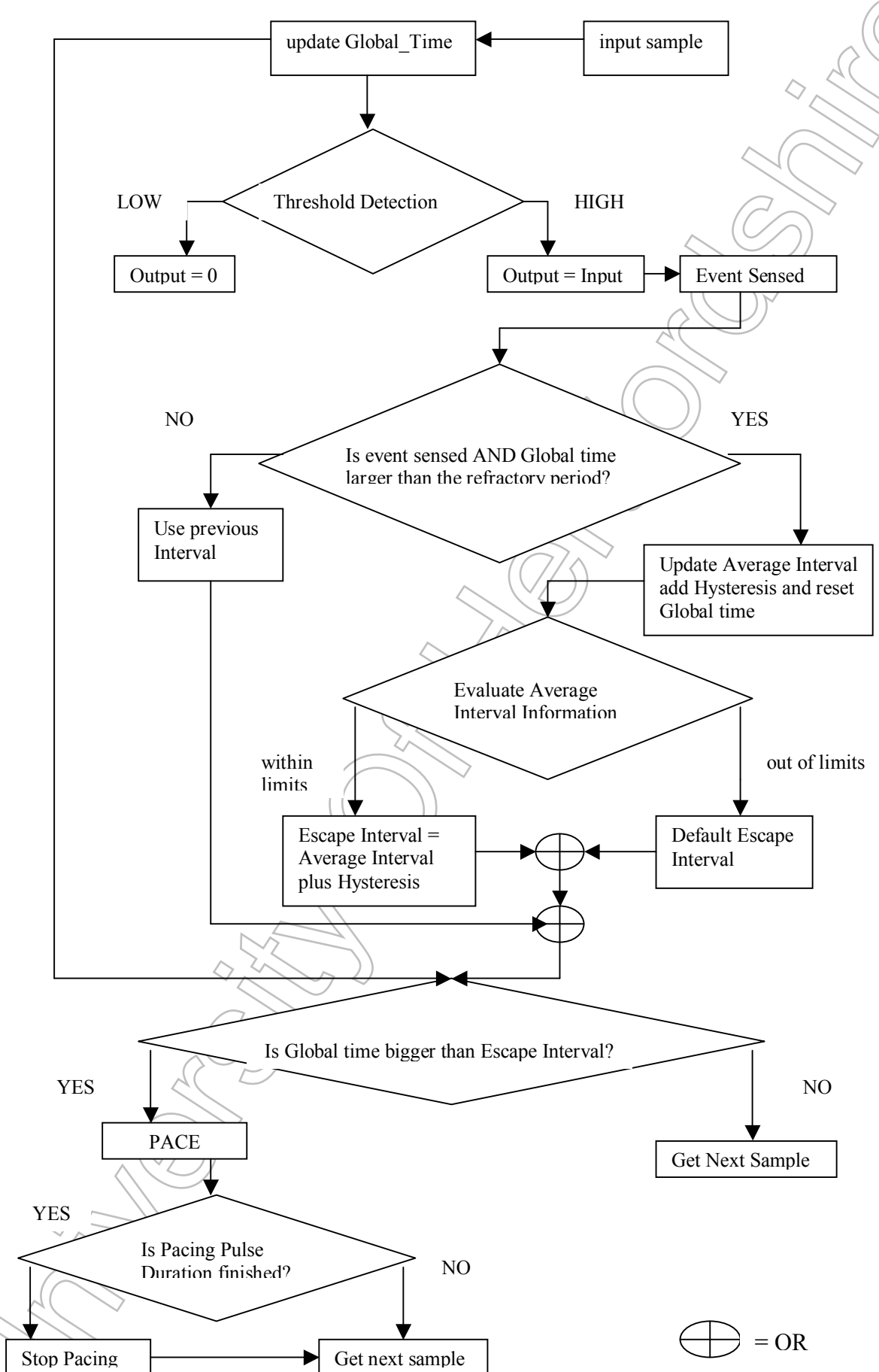

Figure 7.3 The pacemaker algorithm.

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7.4 Shortcomings and Evaluation of Code

Most of the discussion in this section concentrates on the source file dss_cisr which can be found on Appendix 3. There is were the intervention made to the example program to accommodate for the pacing algorithm. It was done in the body of the ISR which serves the ADC. ISRs in general should do something very quickly (pass a value, check a variable) and then finish. If they are too long they might cause problems with the next ISR or they might not let other processes to run, since they have the highest priority. In the case of this program processing within the ISR did not cause any conflict. For two reasons. The processing demands of the algorithm are low. The DSP executes instructions very fast.

There are too many global variables in the code. C++ theory states that global variables are bad practice due to reduced programmed readability because functions do not clearly indicate to the reader what parameters are passed into or out[14]. For two reasons global variables can be justified in the program. Information needs to be retained in between calls to the ISR, especially for timing variables. Readability of functions is not reduced as only one function is accessing them, and that function is on the same source file as the one that the global variables are declared.

Code was written in C so as to be transpotable to other devices.

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Chapter 8 Results

After discussing the algorithm in the previous chapter the presentation of the system is complete. In this chapter the results obtained from the system are presented.

The approach followed is to test the system with all types and combinations of waveforms available from Heartsim. Results were observed on TCSCOPE. Natural beats and pacing pulses appear on the same graph. Graphs are shown selectively to clarify responses in difficult to explain combinations of waveforms.

The general rule is that the pacemaker should respond to natural waveforms of rate below 60 bpm by firing a pacing pulse.

Pacing pulse width is deliberately wider to help visualization on screen and distinguish it from natural beats. In the results presentation emphasis is given on sequences that require pacemaker treatment.

8.1 QRS Types

The system was tested with the different QRS types provided by the Heartsim running at their default rate of 80 beats per minute (bpm) to check if it performs what was expected. In all cases it was expected that the pacemaker be inhibited at 80 bpm.

Table 8.1 QRS Types and Pacemaker Response

QRS Type	Rate (default)	Expected	Result
A	80	Inhibited	Inhibited
B	80	Inhibited	Inhibited
C	80	Inhibited	Inhibited
D	80	Inhibited	Activated
E	80	Inhibited	Inhibited
F	80	Inhibited	Inhibited
G	80	Inhibited	Activated

As it can be seen the system has a problem recognising QRS types D and G. They are both Bundle Branch Blocks. Type D represents a Bundle Branch Block with broad R wave and inverted T wave (see Figure 8.1). Type G represents a Bundle Branch Block with broad S wave and upright T wave (see Figure 8.2).

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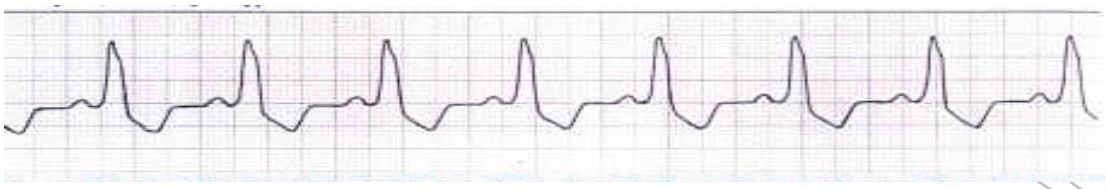

Figure 8.1 Normal Sinus Rhythm, rate 80, QRS Type D.

Figure 8.2 Normal Sinus Rhythm, rate 80, QRS Type G.

Bundle branch blocks are disorders of the conduction system. They cause delay of impulse propagation from the atria to the ventricles. Bundle branch blocks involve failure of some portion of the intra-ventricular conduction system. They do not lengthen the P-R interval as 1^{o} block, but the they delay the conduction of the pulse within the ventricles. That is why the QRS is broad. Depending on the particular site of infection, either the Q-R interval lengthens (type D), or the R-S interval lengthens (type G). This is rarely a problem but leads to an abnormal ECG pattern that may make the detection quite difficult[15].

Two cases can cause the system not to detect a natural beat.

a) The QRS is not of high enough amplitude to overcome the amplitude threshold and reset the pacing timer.

b) The QRS is too broad and exceeds the refractory period limit (Appendix 3, dss_cisr, "Calculate Interval" section, second argument on "if" statement GLOBAL_TIME>=1000). Thus, the same QRS is counted as two. The interval in between them is very small, falls out of the absolute limit (Appendix 3, dss_cisr, "Calculate Interval" section hysteresis>5000) and standard pacing rate takes place (Appendix 3, dss_cisr, "Calculate Interval" section else escape_interval=6000). The standard pacing rate is 60 bpm.

The second case holds true for bundle branch blocks because they are too broad. Tests were made with progressively increasing refractory period limit and types D and G were recognised. That came with strings attached in that other waveforms were not recognised. That holds for mild tachycardias, which might be due to physical exercise. In that case two pulses were interpreted as one because they were happening within the refractory (blind) period. The output was half the rate.

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Refractory period is the period that starts at the onset of the action potential during which a subsequent impulse cannot stimulate the cell[16].

8.2 Basic Rhythms

In this section all basic rhythms with all QRS types are tested to see if the pacemaker functions as expected under all circumstances.

8.2.1 QRS Type A

Type A QRS complex is a normal upright QRS T (Figure 8.3).

Figure 8.3 Normal Sinus Rhythm, rate 80, QRS Type A

The columns "expected" and "result" refer to the state of the pacemaker. Activated means it is pacing at regular intervals or when needed. Inhibited means there is no pacing at all. In most cases, the estimate of what was expected was based on the rate only.

Table 8.2 QRS Type A in different rhythms and rates

Rhythm	Rate	Expected	Result
Sinus Bradycardia	30	Activated	Activated
	40	Activated	Activated
	50	Activated	Activated
Normal Sinus	60	Inhibited	Inhibited
Rhythm (NSR)	80	Inhibited	Inhibited
Sinus Tachycardia	100	Inhibited	Inhibited
	120	Inhibited	Inhibited
	140	Inhibited	Inhibited
Atrial Tachycardia	90	Inhibited	Inhibited
	180	Inhibited	Inhibited

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	260	Inhibited	Inhibited
Atrial Flutter	75	Inhibited	Inhibited
	100	Inhibited	Inhibited
	150	Inhibited	Inhibited
Atrial Fibrillation	40	Activated	Activated
	90	Inhibited	Inhibited
	180	Inhibited	Inhibited
Junctional	30	Activated	Activated
	80	Inhibited	Inhibited
	180	Inhibited	Inhibited
Ventricular (note 1)	120	Inhibited	Activated
Tachycardia	180	Inhibited	Activated
	210	Inhibited	Activated
Ventricular (note 2)	Very Coarse	Activated	Activated
Fibrillation	Standard	Activated	Activated
	Very Fine	Activated	Activated
Asystole		Activated	Activated
1^o AV block	40	Activated	Activated
	60	Inhibited	Inhibited
	85	Inhibited	Inhibited
2^o AV block #1	5:4 (slow)	1 paced, 4 natural	1 paced, 4 natural
	4:3	note 3	note 3
	3:2 (fast)	1 paced, 2 natural	1 paced, 2 natural
2o AV block #2	3:1 (slow)	note 4	note 4
	2:1 3:1	interchanged	interchanged
	2:1 (fast)	1 paced, 1 natural	1 paced, 1 natural
3o AV block	30	Activated	Activated
	50	Activated	Activated
	60	Inhibited	Inhibited

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Notes:

1) Ventricular Tachycardia

Defined as three or more consecutive ventricular ectopic beats[13] (see Figure 8.4). The QRS is broad and "different" from supraventricular complexes. Rhythm is regular or nearly regular. Atrial rhythm is usually slower and undisturbed by the rhythm of the ventricles.

Sustained ventricular tachycardia is a life threatening arrhythmia and definitive treatment should be instituted immediately[17].

The programming of the pacemaker does not include any anti-tachy-arrhythmia functions. However, it fires pacing pulses when it has as input ventricular tachycardias waveforms. That is desirable as a treatment. Pacemaker pulses, properly timed and placed, can terminate ventricular tachycardia . Such treatment can also elicit fibrillation.

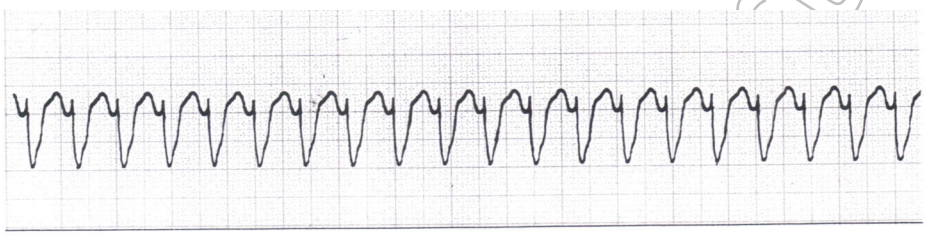

Figure 8.4 Ventricular Tachycardia, rate 180, QRS type A

2) Ventricular Fibrillation.

Rapid irregular rhythm with chaotic undulations without a P-wave, QRS, ST segment or T-wave (see Figure 8.5). It represents lack of organised ventricular depolarisation.
Result: Pacemaker is active. It does not interpret any part of the waveform as a QRS complex (correctly). It fires a pacing pulse at regular intervals. It is not a substitute to a cardioverter/defibrillator but it can in some cases terminate the fibrillation.

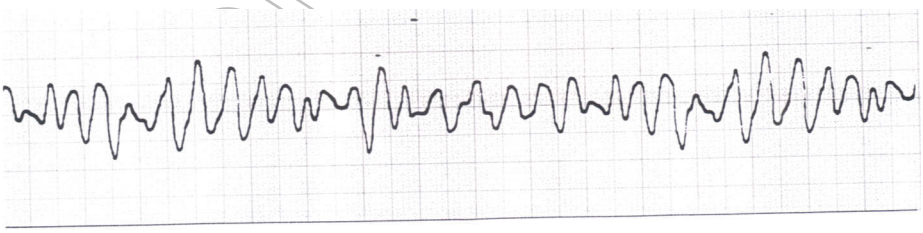

Figure 8.5 Coarse Ventricular Fibrillation

8.2.2 QRS Type B

Type B QRS complex is an upright QRS with ST depression and T inversion.

Table 8.3 QRS Type B in different rhythms and rates

Rhythm	Rate	Expected	Result
Sinus Bradycardia	30	Activated	Activated
	40	Activated	Activated
	50	Activated	Activated
Normal Sinus	60	Inhibited	Inhibited
Rhythm	80	Inhibited	Inhibited
	100	Inhibited	Inhibited
S. Tachycardia	120	Inhibited	Inhibited
A. Tachycardia	180	Inhibited	Inhibited
A. Fibrillation	90	Inhibited	Inhibited
Junctional	80	Inhibited	Inhibited
V. Tachycardia	180	Inhibited	Activated
V. Fibrillation		Activated	Activated
1o AV block	40	Activated	Activated
	60	Inhibited	Inhibited
	85	Inhibited	Inhibited
2o AV block #1	5:4 note 1	1 paced, 4 naturals	1 paced, 4 naturals
	4:3	1 paced, 3 naturals	1 paced, 3 naturals
	3:2	1 paced, 2 naturals	1 paced, 2 natural
2o AV block #2	3:1 note 2	2 paced, 1 natural	2 paced, 1 natural
	3:1 2:1	interchanged	interchanged
	2:1	1 paced, 1 natural	Activated
3o AV block	30	Activated	Activated
	50	Activated	Activated
	60	Inhibited	Inhibited

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Notes

1) 2^{O} AV heart block, Mobitz type 1, 5:4

Definition for Mobitz type 1 2^{o} AV block states that P-R intervals are actually prolonged until conduction fails and then the node recovers[15]. A 5:4 conduction ratio means 5 P-waves to 4 QRS complexes. Figure 8.6 shows a representative waveform of QRS type D. The emphasis is on the sequence of conducted and non-conducted QRSs'.

Figure 8.6 2nd degree block (type 1, 5:4 conduction ratio). Source: Heartsim 2000 User Manual.

Expected result is 1 paced pulse for 4 naturals. Figure 8.7 shows the result. It can be observed that the second and the last pacing pulses are occurring as expected. The interval between the first and second natural beats is 2.2 sec. This is where the P-wave was not conducted. The interval between the third and the second heartbeat is 1.7 sec (~35 bpm) and pacing is justified. The interval between the fourth and third natural beats is 1.6 sec, pacing again justified. The interval between fifth and fourth is again 1.6sec and pacing is justified again. Pacing pulses are happening just before the natural pulse. That is because our variability measure is 10% and extends the waiting time. Natural beats terminate pacing both in real pacemakers and here.

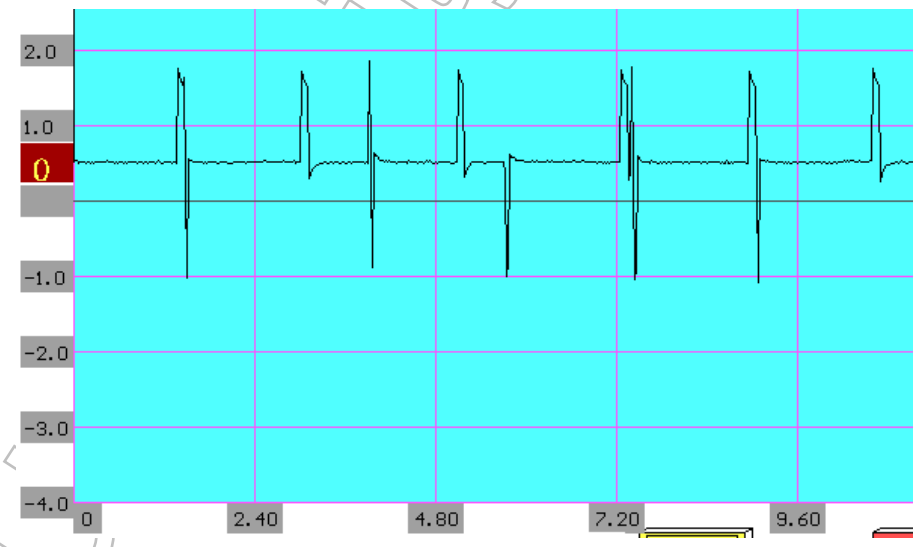

Figure 8.7: 2nd degree block (type 1, 5:4 conduction ratio). Natural beats appear biphasic and one appears negative due to sampling problems with the 711 data acquisition card. All paced pulses appear positive and wider. Vertical axis units are volts. Horizontal axis units are seconds.

4) 2^{O} AV heart block, Mobitz type 2, 3:1.

Definition of 2^{o} AV block Mobitz Type 2 states that some atrial impulses will fail to conduct a ventricular contraction[15]. Some P-waves are not conducted. A 3:1 conduction ratio means that we have 2 non-conducted P-waves to 1 conducted QRS. In between these cycles we might have sequences of normally conducted pulses. Figure 8.8 shows a representative waveform of QRS type B. The emphasis is not on the QRS type but on the sequence of conducted or non conducted pulses.

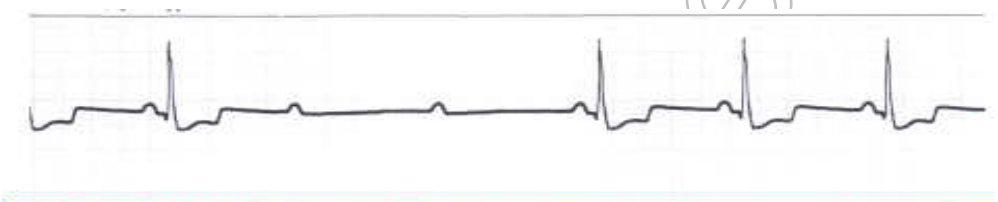

Figure 8.8 3:1 conduction ratio of 2^{o} AV block Type 2. Source: Heartsim 2000 User Manual.

Figure 8.9 shows the result of applying to the pacemaker such a waveform. It can be seen that for the two non-conducted P-waves the pacemaker takes control and replaces the natural beats. Whenever there is a natural beat the pacemaker is inhibited. Hence, the operation of the pacemaker under such a waveform is considered successful.

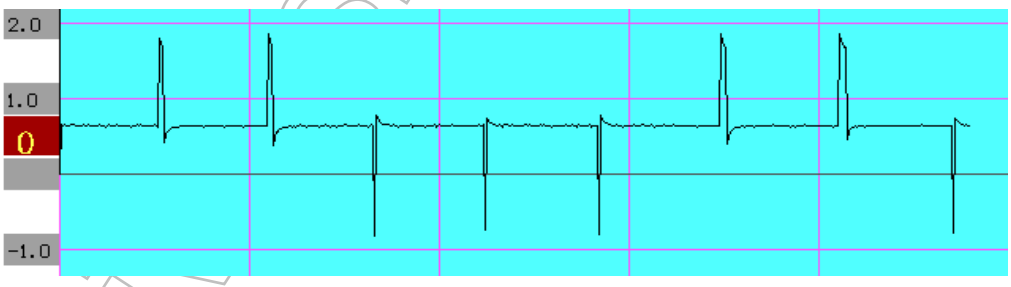

Figure 8.9 3:1 conduction ratio of 2^{o} AV block Type 2. Natural beats appear inverted. Pacing pulses appear positive and wider.

8.2.3 QRS Type C

Type C QRS complex is an upright QRS with ST elevation (see Figure 8.10).

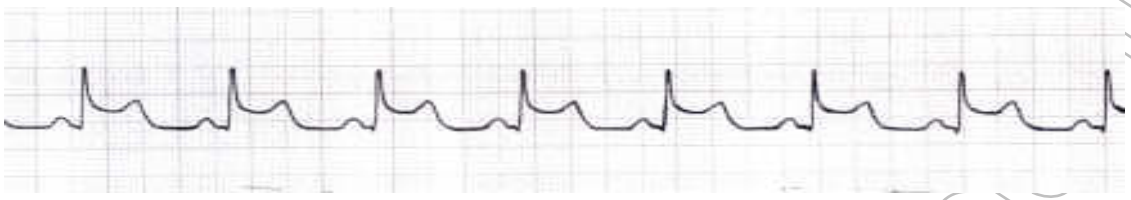

Figure 8.10 Normal Sinus Rhythm, rate 80, QRS Type C

Table 8.4 QRS Type C in different rhythms and rates

Rhythm	Rate	Expected	Result
Sinus Bradycardia	30	Activated	Activated
	40	Activated	Activated
	50	Activated	Activated
Normal Sinus	60	Inhibited	Inhibited
Rhythm	80	Inhibited	Inhibited
	100	Inhibited	Inhibited
S. Tachycardia	120	Inhibited	Inhibited
A. Tachycardia	180	Inhibited	Inhibited
A. Fibrillation	90	Inhibited	Inhibited
Junctional	80	Inhibited	Inhibited
V. Tachycardia	180	Activated	Activated
V. Fibrillation		Activated	Activated
1o AV block	40	Activated	Activated
	60	Inhibited	Inhibited
	85	Inhibited	Inhibited
2o AV block #1	5:4	1 paced, 4 naturals	1 paced, 4 naturals
	4:3	1 paced, 3 naturals	1 paced, 3 naturals
	3:2	1 paced, 2 naturals	1 paced, 2 naturals
2o AV block #2	3:1	2 paced, 1 natural	2 paced, 1 natural
	3:1 2:1	interchanged	interchanged
	2:1	1 paced, 1 natural	1 paced, 1 natural
3o AV block	30	Activated	Activated

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	50	Activated	Activated
	60	Inhibited	Inhibited

8.2.4 QRS Type E

Type E QRS complex is a biphasic QRS with T inversion.

Table 8.5 QRS Type E in different rhythms and rates

Rhythm	Rate	Expected	Result
Sinus Bradycardia	30	Activated	Activated
	40	Activated	Activated
	50	Activated	Activated
Normal Sinus	60	Inhibited	Inhibited
Rhythm	80	Inhibited	Inhibited
	100	Inhibited	Inhibited
S. Tachycardia	120	Inhibited	Inhibited
A. Tachycardia	180	Inhibited	Inhibited
A. Fibrillation	90	Inhibited	Inhibited
Junctional	80	Inhibited	Inhibited
V. Tachycardia	180	Activated	Activated
V. Fibrillation		Activated	Activated
1o AV block	40	Activated	Activated
	60	Inhibited	Inhibited
	85	Inhibited	Inhibited
2o AV block #1	5:4	1 paced, 4 naturals	1 paced, 4 naturals
	4:3 note 1	1 paced, 3 naturals	1 paced, 3 naturals
	3:2	1 paced, 2 naturals	1 paced, 2 naturals
2o AV block #2	3:1	2 paced, 1 natural	2 paced, 1 natural
	3:1 2:1 note 2	interchanged	interchanged
	2:1	1 paced, 1 natural	Activated
3o AV block	30	Activated	Activated
	50	Activated	Activated
	60	Inhibited	Inhibited

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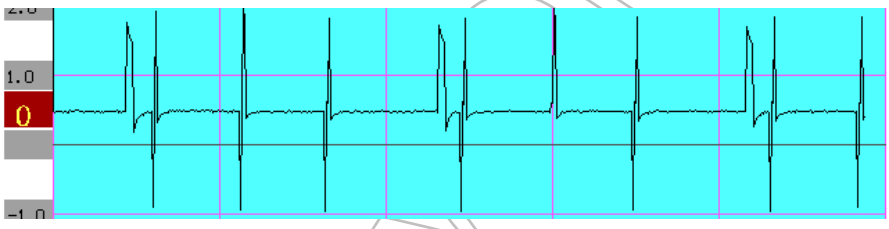
Notes

1) 2^{O} AV heart block, Mobitz type 1

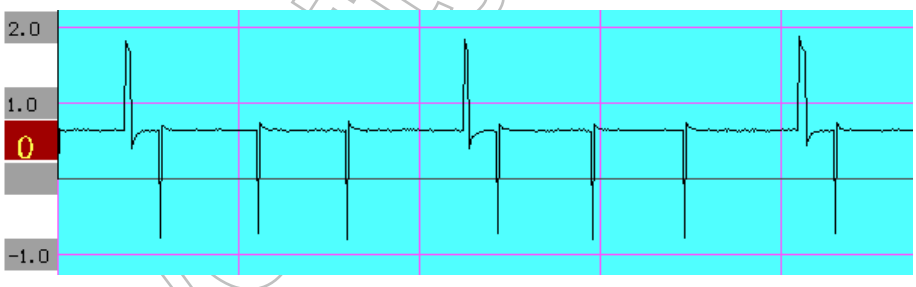
Definition states that P-R intervals are actually prolonged until conduction fails and then the node recovers[15]. A 4:3 conduction ratio means 4 P-waves to 3 QRS complexes. Figure 8.11 shows a representative waveform of 2^{o} QRS Type E. The emphasis is not on the QRS type but on the conduction ratio.

Figure 8.11 4:3 conduction ratio of 2^{o} AV block Type 1. Source: Heartsim 2000 User Manual

The result expected was 1 pacing beat for every 3 naturals. Figure 8.12 shows the result. The pacemaker is functioning as it should. It senses the natural beats correctly. Then it fires a pacing pulse when a natural pulse is missing (the "blank" interval is larger than the average of the three previous intervals plus 10%).



(a)



(b)

Figure 8.12 4:3 conduction ratio of 2^{o} AV block Type 1. Pacing pulses appear positive and wide. (a) QRS Type E. Same type as Heartsim Manual example of Figure 8.11. Natural beats appear biphasic (fifth appears positive). (b)QRS Type A. Natural beats appear inverted.

2) 2^{O} AV block, Mobitz type 2, 3:1/2:1

Definition states that some atrial impulses will fail to conduct a ventricular contraction[15]. Some P-waves are not conducted. A 3:1 conduction ratio means that there are 2 non-conducted P-waves to 1 conducted QRS. A 2:1 conduction ratio means that we have 1 non-conducted P-wave to 1 conducted QRS. These ratios are used interchangeably. Figure 8.13 shows a representative waveform of QRS type E.

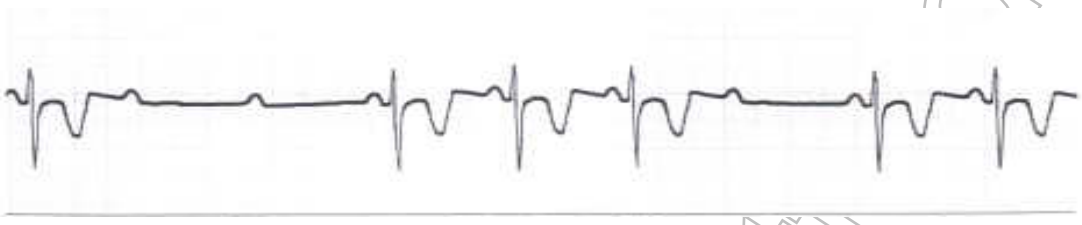


Figure 8.13 2nd degree block (type 2, 3:1/2:1 conduction ratio). Source: Heartsim 2000 User Manual.

It is expected to get 2 paced pulses for 1 natural beat, and 1 paced pulse for 1 natural beat. Some normal pulses appear in between the block sequences, as would happen in a real heart it is not always in a state of block. Figure 8.14 shows the result. The pacemaker pulses successfully replace all the dropped beats at reasonable intervals from the last natural beat.

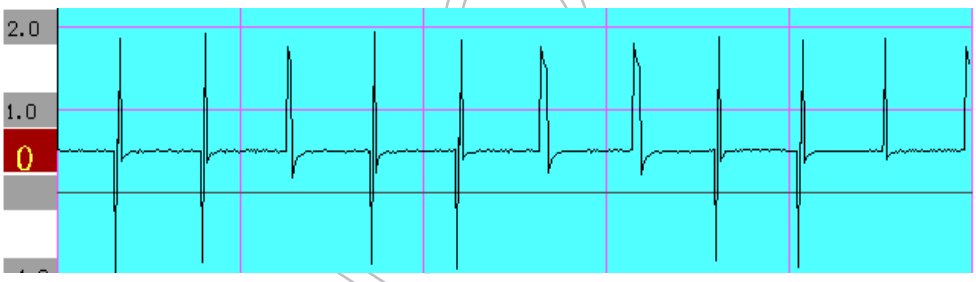


Figure 8.14 2nd degree block (type 2, 3:1/2:1 conduction ratio). Natural beats appear biphasic (last one appears positive). All paced pulses appear positive and wider. Vertical axis units are volts. Horizontal axis units are seconds.

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8.2.5 QRS Type F

Type F QRS complex is a QRS with ST elevation.

Table 8.6 QRS Type F in different rhythms and rates

Rhythm	Rate	Expected	Result
Sinus Bradycardia	30	Activated	Activated
	40	Activated	Activated
	50	Activated	Activated
Normal Sinus	60	Inhibited	Inhibited
Rhythm	80	Inhibited	Inhibited
	100	Inhibited	Inhibited
S. Tachycardia	120	Inhibited	Inhibited
A. Tachycardia	180	Inhibited	Inhibited
A. Fibrillation	90	Inhibited	Inhibited
Junctional	80	Inhibited	Inhibited
V. Tachycardia	180	Activated	Activated
V. Fibrillation		Activated	Activated
1o AV block	40	Activated	Activated
	60	Inhibited	Inhibited
	85	Inhibited	Inhibited
2o AV block #1	5:4	1 paced, 4 naturals	1 paced, 4 naturals
	4:3	1 paced, 3 naturals	1 paced, 3 naturals
	3:2 note 1	1 paced, 2 natural	Inhibited
2o AV block #2	3:1	2 paced, 1 natural	2 paced, 1 natural
	3:1 2:1	interchanged	interchanged
	2:1 note 2	1 paced, 1 natural	Activated
3o AV block	30	Activated	Activated
	50	Activated	Activated
	60	Inhibited	Inhibited

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Notes:

1) 2^{O} AV block, Mobitz type 1, 3:2

In this case there is a 3:2 conduction, 3 P-waves to 2 QRS complexes. Figure 8.15 shows a representative waveform of QRS type F.

Figure 8.15 2^{o} block (type 1, 3:2). QRS Type F. Source: Heartsim 2000 User Manual.

It is expected that the pacemaker fires a pulse every two natural beats. In figure 8.16 the results can be seen. It does fire a pacing pulse for every two naturals but it fires very late.

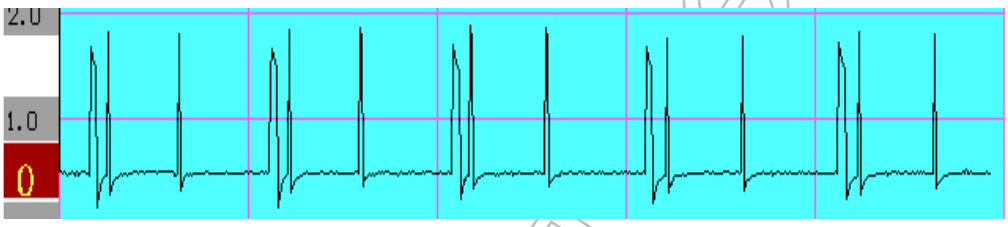

Figure 8.16 2^{o} degree block (type 1, 3:2). Natural beats appear positive and narrower than pacing pulses. Vertical axis units are volts. Horizontal axis units are seconds.

2) 2^{O} AV block, Mobitz type 2, 2:1

With a 2:1 conduction ratio it is expected that the pacemaker would fire one pulse for every natural that is occurring. In figure 8.17 the results are displayed. The pacing pulses fire regular as the natural beats. The pacemaker replaces the dropped beat through the sequence. Operation is considered successful in this case. Ideally the pacing pulses should happen in the middle of the interval of the two natural beats.

Figure 8.17 2nd degree block (type 2, 2:1). Natural beats appear positive and narrow. Pacing pulses appear positive and wider. Vertical axis units are volts. Horizontal axis units are seconds.

8.3 Premature Beats.

8.3.1 Premature Atrial Complexes (PACs)

Premature atrial complexes originate within the atria muscle but outside of the SA node from an ectopic focus[15]. The ECGs' P wave is premature but the QRS complex remains unchanged because AV nodal conduction and ventricular depolarisation. Unless the heart rate is so rapid that the ventricles do not have time to fill properly PACs are not considered a dangerous disarrythmia.

The VVI pacemaker senses the ventricular depolarisation, calculates the average interval of the three previous pulses and reduces it if the beat occurs prematurely. The next normal ventricular depolarisation happens at an interval that is longer than the average interval of the three previous beats (which includes the short premature interval). The waiting time for a depolarisation expires and invokes a pacing pulse. Figure 8.18 shows the events and figure 8.19 shows the results.

Figure 8.18 NSR, rate 80, PACs, QRS Type A

Figure 8.19 Premature Atrial Complexes. QRS Type A. Rate 80.

8.3.2 Premature Nodal (Junctional) Complexes (PJCs)

Premature nodal complexes represent electrical impulses that occur at the AV node or high in the ventricles before the arrival of the next atrial beat[15]. The ECG reveals a P wave that may be prior to, just after, or during the QRS complex, depending on the area of excitation. Treatment is usually not required unless the rate is quite slow and coincident with a failed sinus mechanism.

The premature nodal waveforms available from Heartsim do involve a normal sinus rhythm, hence treatment is not in theory required. However because the QRS happens early in relation to the previous pulse it shortens the average interval. The next QRS is expected from the pacemaker earlier than would otherwise be expected. If the next QRS is not premature it will happen later than the calculated average interval and the pacemaker would fire a pulse. Figure 8.20 shows a representative waveform and figure 8.21 shows the response of the pacemaker when applying such a waveform.

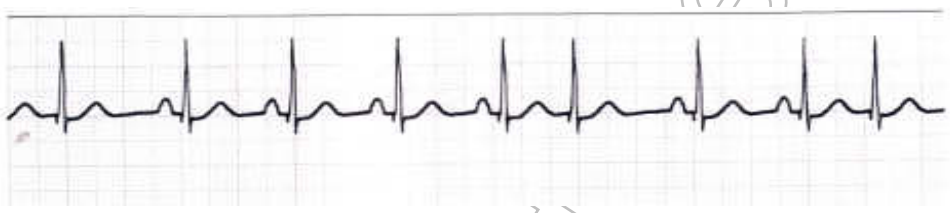

Figure 8.20 NSR, rate 80, PJCs, QRS Type A

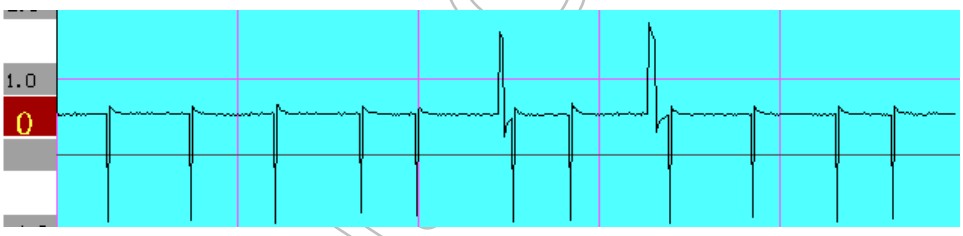

Figure 8.21 Premature Junctional Complexes. QRS Type A. Rate 80. Natural beats appear negative. Pacing pulses appear positive.

8.3.3 Premature Ventricular Complexes (PVCs)

Premature ventricular beats represent ventricular depolarisation that prematurely arises from a site in the ventricular muscle or the conductive system. If the site of impulse initiation is within the common section of specialised conductive tissue, the QRS complex will be slightly widened, since it reflects retrograde and anterograde conduction within the

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ventricles simultaneously[15]. The ECG reveals wide, bizarre QRS complexes. PVCs can signal an increased risk of a more dangerous type of ventricular conduction disturbance. Figure 8.22 shows a representative waveform and figure 8.23 shows the response of the pacemaker when applying such a waveform.

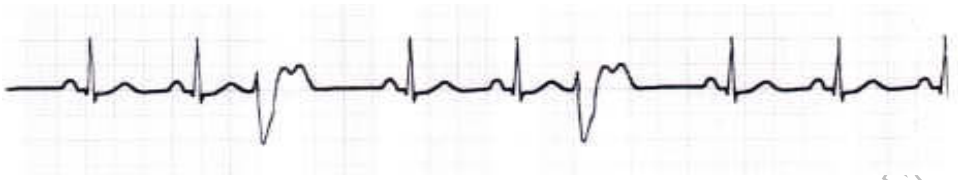

Figure 8.22 NSR, rate 80, Unifocal PVCs, QRS Type A

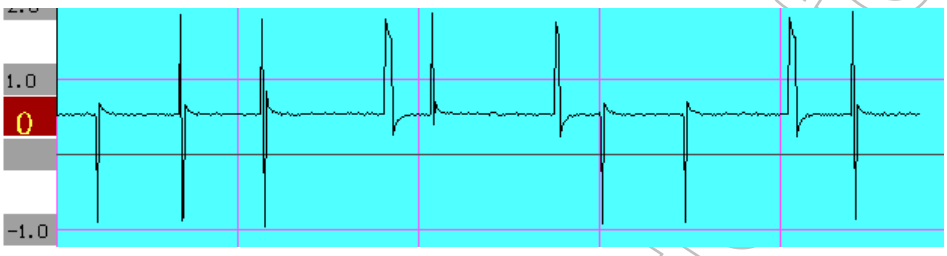

Figure 8.23 Unifocal Premature Ventricular Complexes. QRS Type A. Rate 80. Pacing pulses appear positive and wider.

Section 8.4 Artefacts and Noise

The Heartsim offers the opportunity to test the pacemaker under conditions of noise superimposed on the ECG (see Figure 8.24). Two kinds of noise are offered. 60 Hz - AC line interference (from other machinery) and muscular interference from patient movement. These were superimposed on a variety of waveforms both on their own and combined. All the QRS's were acquired with no distortion at all. The system proved noise resistant. The more obvious explanation is the high level of amplitude threshold. Noise was much lower than that threshold.. However, that might not be the case in a real-world pacemaker. The bandpass filter of the amplifier eliminates any baseline drift effects.

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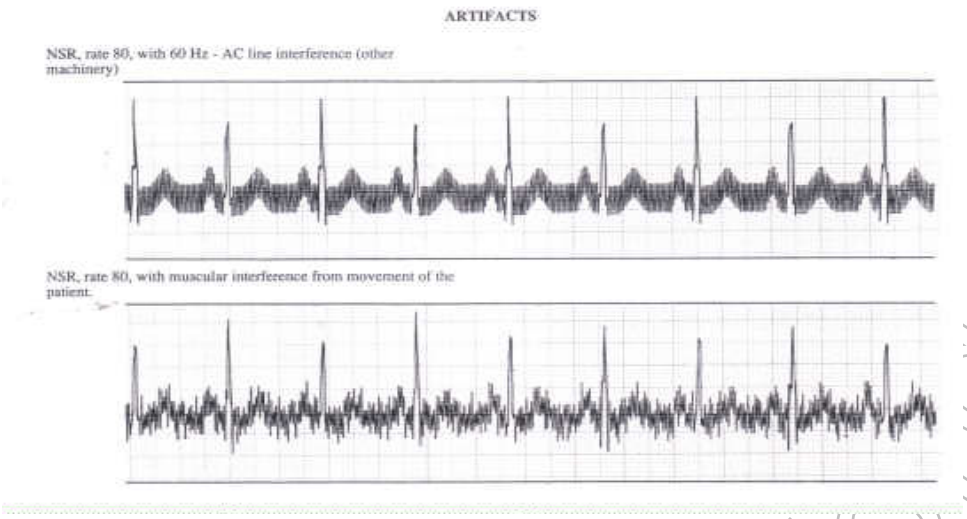
ARTIFACTS
NSR, rate 80, with 60 Hz - AC line interference (other machinery)
NSR, rate 80, with muscular interfeeence from movement of the patient.

Figure 8.24 60 Hz - AC line interference and muscular noise from Heartsim.

Source: Heartsim 2000 User Manual.

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Chapter 9 Conclusions and Discussion

9.1 Summary of work and results

The signal was acquired from the "Heartsim 2000" ECG simulator. It was amplified with an instrumentation amplifier and filtered using a 2nd order Bessel bandpass filter (9-40 Hz bandwidth). Through a 16-bit ADC and a serial port it was fed into the DSP for processing.

The first step of processing is a threshold detector so that only the QRS information remains from the ECG signal. The average time interval between heartbeats is calculated. Some hysteresis is added to that interval. If a pulse does not appear within one second the algorithm activates a pacing pulse. Because of the hysteresis some flexibility is allowed so as to accommodate for normal heart variability.

The output of the system is displayed together with the QRS. Results show rigid performance. The pacemaker is activated whenever heart rate is below 60 bpm and/or whenever a single natural pulse does not appear in less than a second from the previous one.

The pacemaker is activated in very fast ventricular fibrillation and tachycardia although not programmed to. The system does not recognise bundle branch blocks. The system proved noise tolerant. Premature complexes illicit a single pacing pulse. In 2^o AV blocks the pacemaker is activated when beats are missed and inhibited when beats were present. In 3^o AV blocks the pacemaker is always active. In all rhythms that the pacemaker was expected to remain inhibited it did so.

9.2 Objectives and how they were met

The objective that was set to achieve was for the system to fire a pacing pulse whenever there is no QRS or when it occurs at very long intervals. The objective was met in a very high degree. Pacing is activated whenever the heart rate is below 60 bpm and/or whenever a single natural pulse fails to appear within about 1 second. For VVI modalities the response of the pacemaker on 2o AV block is critical as it is under that condition that VVI pacemakers are prescribed. The response of the pacemaker in 2o AV blocks Type 1 and 2 was excellent as it can be seen from sections 8.2.2, 8.2.4, and 8.2.5.

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9.3 Time Plan and Cost

The time plan as was set in the feasibility report was not followed exactly. There was considerable delay in getting started with the DSP board (look Appendix 2 Problems with the DSP). Three quarters of the time were spent troubleshooting the DSP. During that period the algorithm was developed in paper. When the problems with the DSP were solved the algorithm was implemented quickly and successfully.

The equipment used was not bought specifically for the project. The only costs made are the 7 TL071 op-amps costing £0.30 each.

There is no commercial viability of the project as it stands now.

9.4 Suggestions for future work and Improvements

Having as basis the pacemaker presented in this report the most obvious way to go further is to incorporate with a cardioverter/defibrillator. This is most interesting as there is still research going on, unlike the pacemaker. To incorporate a cardioverter/defibrillator the system must be able to recognise arrhythmias. Arrhythmia recognition is an evolving field and there are numerous methods to experiment with. The ‘C6211 is able to support the heavy computational demands that many algorithms command.

To proceed further it is assumed that one finds the system presented here satisfactory. To test it under more realistic conditions another signal generator must be found, since Heartsim gives only idealistic waveforms. The standard ECG libraries that have been developed form the standard test for all implantable devices. One thing that might need changing in the algorithm is to add variable threshold instead of the constant employed here. Maybe a more sophisticated approach for threshold detection is needed such as the time averaging or successive high-pass filters.

9.5 Conclusion

Pacemaker technology is a well established field for a couple of decades now. This project did not intend to be a cornerstone on human knowledge. It was rather a means to an end, a basis for further work. Arrhythmia recognition algorithms are an evolving field. Before the project started it was hoped that there would be some time left to touch on the subject (Probability Density Function for a start). That is why a fast DSP was chosen. But the

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specific DSP was responsible for considerable delay. Time was lost troubleshooting things not directly related to the project.

The pacemaker presented in this report might not be the presented the most exciting thing you have seen but at least it worked.

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